

RESPONSE PAPER

Public Consultation - Registered medical practitioners who provide medical and surgical procedures (17th March, 2015)

Presented by:

ASC Master Franchise Pty Ltd trading as Australian Skin Clinics

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY	3
2. KEY FINDINGS	4
3. ABOUT AUSTRALIAN SKIN CLINICS	6
4. TRAINING OF REGISTERED NURSES AND NURSE PRACTITIONERS	7
3.1 RECRUITMENT OF NURSES	7
3.2 PROFESSIONAL TRAINING INDUCTION PROGRAM	7
3.3 ON-GOING PROFESSIONAL TRAINING AND DEVELOPMENT	8
5. AVAILABILITY OF SUITABLE COURSES/EDUCATION FOR COSMETIC INJECTABLES	9
6. TELEMEDICINE CLIENT CONSULTATION	10
7. COMPLIANCE PRACTICES	12
8. ADVERSE EVENTS	13
9. INCREASED REGULATION AND THE EFFECTS ON COMPETITION	15
10. OVERSEAS INITIATIVES	17
8.1 THE UNITED STATES OF AMERICA	17
8.2 NEW ZEALAND	18
11. POSSIBLE IMPLICATIONS OF A HIGHER REGULATORY FRAMEWORK	19
11.1 ONLINE INJECTABLES	19
11.2 COST TO SMALL BUSINESS	19
12. LASER TREATMENTS	21
13. RECOMMENDATIONS	22
14. CONCLUSION	30
15. SUPPORTING EVIDENCE/TESTIMONIALS	31
16.1 [REDACTED]	
16.2 [REDACTED]	
16.3 [REDACTED]	
16.4 [REDACTED]	

1. EXECUTIVE SUMMARY

This submission is a response to the paper released by the Medical Board of Australia on 17th March, 2015 *Public Consultation - Registered medical practitioners who provide medical and surgical procedures*. We thank you for the opportunity to submit our thoughts on the proposed options that have been outlined in the paper.

While the vast majority of the consultation paper is concerned with major surgeries or procedures that involve cutting beneath the skin. Australian Skin Clinics (ASC) provides minor (non-surgical) procedures that do not involved cutting beneath the skin, for example:

1. Cosmetic injectables;
2. Laser skin treatments;
3. Laser hair removal; and
4. Chemical peels.

The primary areas of the consultation paper that Australian Skin Clinics' will address are:

1. The fact that current Nurse Practitioner education program does not include cosmetic procedures and as such more training and experience in required in this area.
2. Mandatory face-to-face consultations before prescribing an S4 cosmetic injectable.
3. A seven-day cooling off period and how this will impact upon minor non-surgical procedures.

The scope of this submission does not relate to major cosmetic medical and surgical procedures, plastic or reconstructive surgery.

We support the review of industry practices, and in fact would welcome an invitation to participate in a more comprehensive review to discuss minor non-surgical procedures and how the industry can set guidelines and regulations to lift the standard of service delivery amongst all industry providers. We feel this is necessary to maintain the integrity and quality of the delivery of minor non-surgical procedures with all industry providers, ensuring the core focus and primary objective is consumer protection, care and treatment outcome.

The aesthetic market is one of growing consumer demand and we are mindful of the delicate balance between regulatory safeguards and stifling competition.

Throughout this submission, we will highlight the Australian Skin Clinics' practices, as we believe that we have set a superior benchmark for the industry, and despite this, still believe there is room for improvement. In addition to our extensive protocols for all aesthetic treatments and procedures, Australian Skin Clinics has a "Ten Point Client Care Protocol" that is heavily trained and enforced at all our clinics as a strict requirement to ensure that the client is protected by comprehensive safety measures and that their best interests are always paramount and enforced by quality control measures.



2. KEY FINDINGS

A summary of the key items highlighted in this response include:

1. Safety and care of clients who are injected by registered nurses

- Enforcing face-to-face consultations does not guarantee greater safety, service or outcome to consumers.
- The medical practitioner, regardless of whether they are a Doctor or Nurse, requires further training on the administering of cosmetic injectables.

2. Safety of the cosmetic injectable S4 drug

- In the last 20 years there has been no deaths by cosmetic injectables.
- The two most common anti-wrinkle injections used in Australia – Dysport and Botox represent 109 of the adverse drug reactions (ADRs) listed on the Therapeutic Goods Association (TGA) website. By comparison, Paracetamol has recorded 809 ADRs listed and over 60 deaths for the same period.

3. Minimal adverse events and issues with consumer expectations

- Across 15,000 injectable treatments, Australian Skin Clinics experienced undesirable outcomes for 0.172% (26) of treatments.
- Issues with customer expectations represented 0.053% (8) of all injectable treatments for the 15,000 injectable treatments.
- In most instances client expectations can be rectified with further treatment. In others where such action is not possible, the client understands that the product is not permanent and will dissipate over time.

4. Safety of using a Nurse to administer cosmetic injectable S4 drug

- Nurses are increasingly being utilised as trusted and skilled medical professionals for higher level medical procedures to fill the gaps Australia is experiencing with Medical Practitioners.
- Nurses are routinely and commonly used in the reinforced training of inexperienced medical residents, and their recommendations trusted by Doctors.
- There is no proof that medical supervision, whether face-to-face or through telemedicine will affect the outcome of the treatment.

5. Telemedicine practice as a safe method of Nurse supervision

- Telemedicine is the only auditable way of measuring compliance of supervision of Nurses.
- Telemedicine has the opportunity to be more systemised and procedural. It also allows for the undivided attention on the consumer.

- Enforcing mandatory face-to-face consultations may result in increased lack of compliance in the industry resulting in potential harm to consumers with “backyard operators.”

6. Economic impact of mandatory face-to-face consultations

- This would impact affordability of cosmetic injectables considerably.
- The risk is that consumer will actively look online for cost effective home treatments.
- Many businesses would not be able to take on the additional costs and as such will effect financial viability of local small businesses in the marketplace.
- The primary impact would actually be on providers who are delivering injectables as their core service, rather than provider who offer it as a secondary service to their core business. Meaning that the most experienced (delivering injectable most frequently in volume) would be removed from practice.

3. ABOUT AUSTRALIAN SKIN CLINICS

Australian Skin Clinics is one of the largest medi-aesthetic franchise operations in Australia, with eighteen locations in Victoria, News South Wales and Queensland. Established in Ashmore Queensland in 1996 and later franchised in 2011, Australian Skin Clinics has developed a robust system that enforces compliance of medically developed treatment protocols and exceptionally high service delivery that is focused on client care. In fact, our company motto is “To always act in the best interest of the client”, meaning we focus heavily on risk mitigation and protection of our consumers.

The company offers only minor non-surgical procedures such as laser hair removal, laser rejuvenation, cosmetic injectables, microdermabrasion, skin peels, dermal stamping and advanced skin care. These services are all provided in a professional, ethical and service-orientated environment.

We are a franchise business that offers in-demand services to a growing market in a safety-focused environment geared to the well-being of consumers. Importantly, the cosmetic injectable treatments we offer are elective and non-permanent and all injectable products we use are short term. In particular, our fillers will either naturally dissipate over time or can be dissolved with hyaluronidase. Further, we only offer injectable treatments which have the lowest risk-profile, meaning we exclude treatments such as the injection of filler across the nasal bridge, where there is a higher risk of adverse event, such as a vascular occlusion.

The Australian Skin Clinics’ Franchise Model is strictly governed by the Franchising Code of Conduct. All of our eighteen clinics operate as small business, with fewer than ten staff per clinic.

Across the brand, there are nearly 200 employees, including:

- 20 Clinic Managers;
- 12 Clinic Assistants / Receptionists;
- 22 Registered Nurses / Nurse Practitioners;
- 54 Dermal Technicians;
- 53 Laser Technicians;
- 6 Senior Laser Technicians;
- 27 Operational and Administrative Specialists at Head Office; and
- 5 Doctors.

Our team of Doctors include a Medical Director and four Medical Advisors who provide the telemedicine consultations to each of our clinics. The Medical Director oversees the provision of telemedicine consultations and arranging physical consultations where necessary, as well as overseeing our treatment protocols.

Australian Skin Clinics has developed stringent guidelines and protocols for their services to ensure that there is a high benchmark for safety, quality and client care when performing minor non-surgical procedures. The company has a training academy that delivers on-going theory and practical training for all clinics and employees designed to ensure that all protocols and practices are trained, reinforced and monitored for compliance. Our investment in the delivery of safe and effective treatments for our clients is considerable.

4. TRAINING OF REGISTERED NURSES AND NURSE PRACTITIONERS

Australian Skin Clinics uses multiple resources to ensure that our Nurses administer cosmetic injectable treatments safely. They are guided by a Medical Director and have access to a medical team at all times for advice. Australian Skin Clinic Nurses have extensive on-going professional training and development opportunities. Their practice is 100% auditable and in fact compliance checked by a full time Risk and Compliance Manager at the company's head office. The procedures performed do not involve cutting beneath the skin and are classified as a minor non-surgical procedure.

4.1 RECRUITMENT OF NURSES

At Australian Skin Clinics, we only accept qualified Registered Nurses or Nurse Practitioners as Cosmetic Injectors, who are selected following a rigorous recruitment process. This recruitment process looks at:

1. Qualifications and certification in the industry;
2. Additional professional development that the Nurse has partaken in. For example, if the Nurse has completed a course for cosmetic medicine, it evidences a commitment to learning and developing in the field of cosmetic medicine.
3. Whether or not they are considering cosmetic injecting as a long-term career goal.
4. Whether they are deemed psychologically stable, meaning that they do not present with any significant psychological issues such as body dysmorphia.
5. The Nurse's ability to understand a consumer's needs and assess the best outcome for treatment.
6. A genuine desire to deliver best outcome for consumers.
7. The ability to follow systems and procedures to ensure the safety and care of the consumer.

4.2 PROFESSIONAL TRAINING INDUCTION PROGRAM

Before a Registered Nurse can treat in our clinics, they undergo a professional training program run by experienced trainers, which cover:

1. Extensive theoretical training and testing;
2. Supplier manuals (particularly contraindications) and best practices guides, followed by testing with a minimum pass rate for quality assurance;
3. Practical training tailored to their skill level of between 40 – 70 hours utilising a range of products, techniques and injectable areas;
4. Three days of training on company protocols and procedures, including client care, stringent treatment protocols and adverse event handling protocol;
5. Introduction to our Medical Director, Medical Advisors and our telemedicine procedure;
6. Australian Skin Clinics' fifty page Cosmetic Injector Procedure and Compliance Manual, and

7. Australian Skin Clinics' comprehensive treatment protocols focused on client care, safety and best outcome of treatments.

4.3 ON-GOING PROFESSIONAL DEVELOPMENT AND TRAINING

Once a Nurse has successfully passed their training requirements they are approved to commence treating in clinic, and are provided with on-going professional development, which includes:

1. On-going training at the Australian Skin Clinics Training Academy (this is utilised weekly with our Doctors and Nurses);
2. In-clinic training (experienced Cosmetic Injector Trainers visit our clinics to provide on the ground injecting support and training opportunities);
3. 24/7 medical support and advice from an experienced, trained Triage Nurse;
4. 7 day support from a Medical Director and a team of four Medical Advisors;
5. Access to Cosmetic Injector Manual and treatment protocols. These protocols cover all aspects of pre and post care treatment, including an understanding of potential complications and side effects. The Cosmetic Injector Manual highlights after-care for clients who experience an adverse event and these events are monitored by ASC head office to ensure best client outcome is achieved;
6. Work-shops, conferences and formalised training seminars; and
7. Compliance testing, spot exams and skill gaps analysis on a regular basis.

5. AVAILABILITY OF SUITABLE COURSES/EDUCATION FOR COSMETIC INJECTABLES

Training in the administering of cosmetic injectables is an area in which Australian Skin Clinics believes Australia needs better and more suitable education and learning opportunities. The current availability of courses and training is not easily accessible or not suitable. Whilst Australian Skin Clinics have set its own benchmarks in training and education for its Nurses, there is no industry standard.

Australia needs to revise the courses and education made available to support the growing area of cosmetic injectables and cosmetic medicine. It is in the best interest of the medical profession to help facilitate the professional development of Nurses in this area due to the threat of population growth on the country's medical resources.

The primary issues with training in Australia are:

- No Short Courses with a suitable level of both theoretical and practical training. Current courses do not have suitable enough focus on practical training.
- Longer courses are too cumbersome, too lengthy and act as a deterrent for Nurses to upskill.

Training and education is a massive opportunity to develop to strengthen this industry and the service levels provided across the country.

6. TELEMEDICINE CLIENT CONSULTATION

The consultation paper highlights concerns regarding the quality of a consultation if telemedicine is used. There seems to be a concern that client care is reduced if the supervising Doctor is not physically present, and that they appear only through video consultation.

In Australian Skin Clinics' experience, the consultation process for telemedicine is significantly more structured, thorough and in fact auditable, than some of its competitors who offer face-to-face consultations. Perhaps a symptom of the company's business model - being that it is a franchise operation – and as such the company has strong systems and procedures that drive the brand and service consistency for the well-being and satisfaction of clients.

Further, ASC have a seven day roster of Medical Advisors whose sole purpose is to supervise the Registered Nurses who administer cosmetic injectables. This has worked well for our Nurses, who have the undivided attention of trained medical professionals for the sole focus of client care and best treatment outcome. This requires considerable investment by the company, however, we feel it is important that we were not utilising Doctors who have other competing priorities or distractions and that our Doctors have time to spend with our Nurses and clients. This includes adding their own client notes, checking compliance of Nurses and providing full focus to the client. The dual approach of having both the Medical Advisor and Nurse conducting the consultation has the benefit that both parties scrutinising the merits of the procedure before it is conducted.

To ensure a thorough consultation process, Australian Skin Clinics conducts the following procedure, which is documented in scripts for the Doctor and Nurse to ensure they ask the right questions:

1. The Client meets with the Nurse who:
 - (a) Assesses the client's needs and concerns;
 - (b) Assesses whether the client's expectations are achievable;
 - (c) Discusses medical history and current medications;
 - (d) Conducts a physical assessment;
 - (e) Discusses risks and benefits in order to obtain informed consent;
 - (f) Makes a judgement on whether the client is a suitable candidate for the treatment, and if a telemedicine consultation appropriate, or whether a direct physical examination by the Medical Advisor is necessary.
2. The Nurse then contacts the Doctor with the client present, in order for the Medical Advisor to complete the telemedicine consultation. The following procedures is conducted:
 - (a) The Doctor introduces himself and appears "face-to-face" through a live streaming video consultation;
 - (b) The Nurse introduces himself/herself and the client.
 - (c) The Doctor will make the judgement as to whether a telemedicine consultation is appropriate, or whether a direct physical examination by a Doctor is necessary;
 - (d) The Registered Nurse presents the client to the Doctor, providing them with a brief on the client's needs, medical history, medications and background;

- (e) The Doctor asks further questions regarding their medical history and medications used;
 - (f) The Doctor assesses the need for the treatment, to ensure an outcome can be achieved;
 - (g) The Doctor discusses the contra-indications, risks and potential outcomes with the client;
 - (h) The client has an opportunity to ask questions about any concerns about the treatment;
 - (i) The Doctor approves the treatment plan for the client;
 - (j) The client signs their consent to the treatment;
 - (k) A standing order is generated and signed by the Doctor before the treatment commences; and
 - (l) The Doctor uses the "Medical Advisor Template" for client notes in the company's client management system. Our record keeping consists of individual client files where the Doctor must complete five information categories and include any additional notes as deemed necessary; and
 - (m) The Telemedicine consultation is completed.
3. If the Doctor agrees that the treatment is to be conducted, the Nurse proceeds to the next stage of the treatment as follows:
- (a) The Nurse administers the injectables treatment as discussed;
 - (b) The Nurse reinforces expected outcome and side effects;
 - (c) The Nurse provides the client with a Post-care take home information; and
 - (d) The Nurse adds notes to the client's file using the "Nurse Template" requiring 8 pieces of information including units used, areas treated, batch numbers, type of product etc.
4. The Nurse instigates the client follow up as follows:
- (a) The Nurse calls the client the next day to check how they are and addresses any immediate concerns; and
 - (b) The Nurse sees the client in a 10-14 day post care follow up to assess results.

We believe that this process is safe because the shared care between the Doctor and Nurse allows for discussion and scrutiny by both the Doctor and Nurse before the treatment is conducted. All procedures are clearly and thoroughly documented and outlined in the guidelines that they need to follow.

7. COMPLIANCE PRACTICES

This video consultation process works well for Australian Skin Clinics because the entire process is auditable and compliance checks on our clinics and Nurses is a simple and easy one for the company. As mentioned above, we have a full time Risk and Compliance Manager who routinely audits compliance in all manner of company policies and practices, but in particular for cosmetic injectables.

Our integrated technology, provides ease of auditing the following:

- Client File: These are submitted by both the Doctor and Nurse in pre-set information fields that are mandatory fields in the system.
- Standing Orders: Completed online and saved in Client File.
- Before and After Photos: These are collected for quality assurance. These are taken at each appointment and saved in the client file.
- Consultation: Conducted using our Video Conferencing Queuing system. Time stamped and logged.
- Follow Up Care: Our clinics use a “Weekly Compliance Tracker” to check compliance with client care protocols, ascertain client satisfaction levels and outline any client expectation issues.

We use only auditable systems which means we can ensure that our team members are following the correct procedures for compliance and highest level client care.

To demonstrate the benefit of this we compare a medical practice or clinic which utilises a face-to-face consultation. While it is common practice to use auditable client management systems for note taking and storing of standing orders, these practices cannot easily prove that the Doctor has provided direct supervision with the administering Nurse. At Australian Skin Clinics, our technology time stamps every video consultation, highlighting the time, date, duration of the consultation and location of the Nurse so that we can track compliance to our system and protocols.

Further, our business is directly focused on systems and compliance. We would suggest that other practices who provide cosmetic injectable treatments as a minor additional service, amongst many others – being general health or cosmetic medicine practices – may not be as strict with compliance.

8. ADVERSE EVENTS

For risk protection and transparency, Australian Skin Clinics require, as a strict company protocol, that all adverse events be recorded via submission of an “Adverse Event Form” to our Client Care Department at the Australian Skin Clinics’ National Head Office. This is so that adverse events can be monitored and managed to ensure a quick and high quality client care plan developed for the client, to ensure a positive outcome, as well as a quality control check on our training standards.

An adverse event is defined by Australian Skin Clinics as:

Exert from company Operations Manual:

“A complaint or adverse reaction is any outcome a client experiences (or technician witnesses) that appears to be undesirable (whether it is normal or not). Complaints or adverse reactions can appear in the following instances:

1. The client makes a formal or informal complaint;
2. The client alerts you to an undesirable reaction/outcome to their treatment;
3. The client alerts you to a gap in their expectations for the treatment or results;
4. You become aware that the client has experienced an undesirable reaction to their treatment (they may not have noticed); and
5. The client alerts you to a concern they have, but you know that the reaction is normal.”

From the six months between 01 July, 2014 to 31 December, 2014, our business conducted 100,000 treatments across the brand in the minor non-surgical service categories of cosmetic injectables, laser treatments, microdermabrasion, dermal needling and low grade chemical peels. Adverse events recorded for this same period occurred in 0.2% of treatments. However, it is important to highlight that of these adverse events, as per our adverse event recording protocol, a large portion of these were due to client expectations and normal responses.

Adverse events whereby an undesirable outcome was experienced for injectables was 0.172% of total injectable treatments for that period. This includes events such as bruising or swelling.

Cosmetic Injectable Adverse Events by Type of Event

Injectable Summary			
Total Injectable Treatments	15,000		
Clients who needed more product after first treatment	Number	16	% to Total Treatments
Clients whose expectations were not met		8	
Other minor adverse event eg mild lump or mild swelling		15	
Clients who experienced bruising		6	
Clients who highlighted a concern that was actually a normal treatment outcome		5	
Clients who experienced a droop (inc ptosis)		4	
Clients who had a suspected Vascular Occlusion		1	

Of the cosmetic injectables adverse events it is important that over half of the 55 adverse events were due to under-dosing (meaning a top up rectified the issue without further issue) or a normal event. A normal event is an outcome within the standard range of anticipated outcomes, but did not meet client expectation. For example, if dysport is used to the crow's feet area on a client, who presents with deep lines. A normal result may be that the Registered Nurse achieves the desired outcome, meaning no movement of facial muscles in the area, but the deep lines are still somewhat visible. This means the outcome is normal, however the client's personal hopes for the treatment were that the deep lines would become less visible. In this instance, while we know this is a normal outcome, we still treat it as an adverse event as the treatment has not met the client's expectations.

Of the adverse events reported that were due to a genuine abnormal reaction, all but one was a minor event. One suspected vascular occlusion was considered serious, but the treatment, quick, effective and impact to client was minimal.

To protect clients in the event of an adverse event, Australian Skin Clinics ensures all clinics adhere to a strict protocol which is audited and managed by a team of professionals at the company's head office. The way in which Australian Skin Clinics manages client care in the case of an adverse event is exceptional. Extensively documented, as well as audited, Australian Skin Clinics' Nurses have significant support for Adverse Events, including:

- (a) Adverse Event and Complaints Protocol;
- (b) Adverse Event and Complaints Management Flow Chart (Which sets out clear requirements for turn-around of required action by various team members);
- (c) Adverse Event Treatment Protocols – what to do in the event of a specific adverse event, eg. Ptosis;
- (d) An Adverse Event Form submitted online and distributed to Triage Nurse (whom is available 24/7);
- (e) A 7 day per week support service; and
- (f) A Medical Director and team of advisors.

9. INCREASED REGULATION AND THE EFFECTS ON COMPETITION

The Australian Government has recently completed an extensive review of Competition Policy in Australia. Competition policy plays an important role in improving government performance by promoting user choice and encouraging a diversity of providers. Choice and diversity have the potential to improve outcomes for users, especially but not only by stimulating innovation.¹ The recommendations as a result of the Competition review, included that Governments should promote consumer choice when funding, procuring or providing goods and services and enable informed choices by consumers.

As a result of the Policy, the Review Panel recommended that legislation or government policy should not restrict competition unless the benefits of the restriction to the community as a whole outweigh the costs.² Importantly, the review recommended changes to prevent:

1. The imposition of excessive restrictions on the market which may result in the misuse of market power; and
2. Unilateral conduct that substantially harms competition.³

Restrictions on who can be in the market or how they can trade – can deliver less competitive outcomes and narrow consumer choice.⁴ Any change to the status quo within the non-surgical industry would need to pass the Competition Principles Agreement test for regulatory restrictions on competition. New regulation should not restrict competition unless it can be demonstrated that the benefits of the restrictions to the community as a whole outweigh the costs.

There are a number of benefits for the consumer, by allowing greater competition within the market for cosmetic injectables, and other non-surgical procedures. The benefits of greater competition within the market means:

1. That consumers can enjoy the lower prices for products and services as a result of the bulk buying power of the franchise group;
2. Reduced prices means that the products and services are more affordable to the everyday consumer and allows the services to be available across a broader selection of the public;
3. Greater competition requires service providers to offer high quality services to ensure that they continue to get the business;
4. The market for these services naturally is more innovative and efficient;
5. It promotes consumer confidence as increased competition doesn't allow for unethical business practices.

This submission highlights Australian Skin Clinic's costs and benefit argument towards maintaining competition within the injectables industry, provided that certain safeguards are present to maintain public safety. Any regulation should be such that it promotes the health and safety of

¹ Competition Review Final Report, 31 March 2015 pg 96

² Competition Review Final Report, 31 March 2015 pg 97

³ Competition Review Final Report, 31 March 2015 pg 10

⁴ Competition Policy Review Issues Paper, 14 April 2014

consumers, whilst keeping the industry as pro-competitive as possible, with the focus primarily on the outcomes rather than the process undertaken.⁵

Where a Doctor is required to be physically present upon conducting injectables treatments (as opposed to the telemedicine option), our clinics will incur increased staff costs which will need to be immediately passed onto the consumer. This would reduce affordability of these services across the broader public.

The report went so far as to assess the needs of particular industry, in particular the regulatory restrictions imposed upon the provision of medical services. It identified that the use of nurse practitioners or registered nurses to perform a range of functions formerly restricted to medical practitioners. The ability to provide shared care, has enabled the delivery of some health services at lower cost without increased risk to patients.ⁱ In accordance with the report, the imposition of a requirement for face to face consultation for injectable services, would be backward step in the industry.

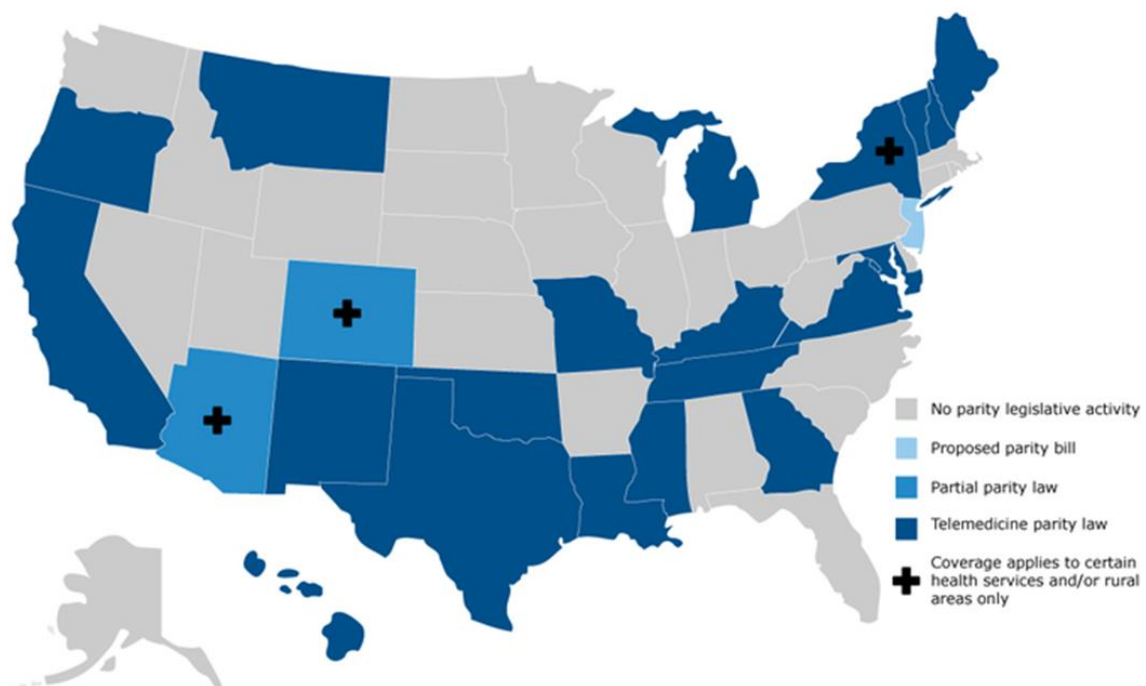
We consider that the Medical Board of Australia should invite the Australian Competition and Consumer Commission to assist in assessing the economic impact of any regulatory changes.

⁵ Competition Review Final Report, 31 March 2015 page 119

10. OVERSEAS INITIATIVES

10.1 THE UNITED STATES OF AMERICA

Throughout the United States of America, telemedicine is routinely becoming a core feature of medical care, across essential and elective medical services. As of January 2015, twenty-two U.S. states currently require insurers to reimburse for telemedicine visits and in-office visits equally (called “parity laws”), and several more states have such legislation in the works. Some state laws only cover certain services or offer coverage to patients in certain locations, but the increasing availability of funding for virtual visits promises to expand this technology into new territories. This map shows the state by state coverage of telemedicine across the United States.



In a study conducted by HIS Abstract (Medical Devices & Healthcare IT), the number of patients taking advantage of telemedical offerings across the world market will increase twentyfold over a five-year period: from 350,000 users in 2013 to 7 million in 2018. According to the American Medical Association (AMA), telemedicine can save between \$300 and \$1,000 per year in claim costs, depending on the size of the family being covered across all medical services.

In California, there have been a number of reviews of the telemedicine legislation for use of telemedicine as an innovative solution to resolve issues with healthcare. Telemedicine has been identified as a means to help reduce the number of patients who miss appointments due to transportation issues or work conflicts, resulting in additional revenue for overbooked primary care physicians.

Importantly though, whilst telemedicine has been actively utilised to alleviate certain physical constraints with patient care, physicians are held to the same standard of care, retain the same responsibilities of providing informed consent, ensuring the privacy of medical information, and any other duties associated with practicing medicine regardless of whether they are practicing via telehealth or face-to-face, in-person visits.⁶

Further, Californian legislation has recently been revised so that there is an requires a health care provider utilising telemedicine at the originating site to inform the patient about the telehealth-delivered care prior to its use, and obtain verbal or written consent, which must be documented.⁷

Interesting, the study also found that sixty-seven percent of patients, combined, respond that using telemedicine “somewhat” or “significantly increases” their satisfaction with their medical care. Just 10 percent report that it “decreases” their satisfaction, and another 23 percent say it has no impact.⁸

10.2 NEW ZEALAND

In 2011, New Zealand’s Ministry of Health adopted the Better, Sooner, More Convenient Health Care approach to healthcare, with the key goal being that this approach would allow for highly trained health professional to focus on people with complex health needs. With this approach to healthcare, it is intended that doctors, nurses and other health care workers work together more closely and in some cases to train others to do certain tasks or procedures.⁹

Examples of this type of healthcare in a practical sense, was provided by GP John Morgan. Steering away from the traditional approach of strictly face to face patient contact, Dr Morgan described the benefit in virtual appointments by way of email or phone, freeing up time for the doctor to develop a care plan for every patient. The benefits of this approach were the provision of care sooner and in a more convenient manner, saving time and money for the patient.¹⁰

Other benefits include:

1. Alleviating the chronic shortage of doctors;
2. Some patients have spoken more freely about medical concerns whereas they may feel embarrassed or ashamed in a face-to-face setting;
3. Where a closer examination is required, doctors use a second handheld video camera;
4. A nurse is present with the patient to ensure that they provide adequate patient support, conduct examinations as required and can aid planning the individualised follow-up care.

⁶ <http://www.mbc.ca.gov/Licensees/Telehealth.aspx>

⁷ AB 809

⁸ <http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/>

⁹ Better, Sooner, More Convenient Health Care in the Community pg5

¹⁰ Better, Sooner, More Convenient Health Care in the Community pg6

11. POSSIBLE IMPLICATIONS OF A HIGHER REGULATORY FRAMEWORK

11.1 ONLINE INJECTABLES

On 19 May 2011, the New Zealand Society of Cosmetic Medicine reported on the increasing incidence of people suffering as a result of do-it-yourself cosmetic procedures.¹¹ The risk is that consumer will actively look online to cost effective home treatments. In some instances, injectables were purchased online with do-it-yourself application kits. Dr Teresa Cattin, president of the New Zealand College of Appearance Medicine, reported seeing patients as frequently as every six weeks, with complications arising from home treatments.

A report by The Australasian College of Cosmetic Surgery estimates the total annual expenditure on cosmetic procedures, including non-surgical treatments, in Australia is around \$1 billion. It is predicted that this will increase by between 15 – 20% over the next 12 months. Of all cosmetic procedures, anti-wrinkle injections, cosmetic and dermal fillers, and laser and IPL top the list for most in-demand.

Registered nurses working within Australian Skin Clinics have reported increasing incidences of consumers experimenting with online injectables as a result of current injectable services being viewed as cost prohibitive. We consider that any proposed reform of the industry take into account the real risk that increased costs within the industry may cause more consumers to investigate illegal online injectables particularly with the increasing demand for injectable services.

11.2 COST TO SMALL BUSINESS

We currently provide Nurses with Doctor availability for fifty-nine hours a week for telemedicine with additional Medical Director hours for reviewing of procedures, training and compliance. We further have out-of-hours medical support available 24/7.

The costs of provision of telemedicine consultation is approximately \$6,000 per week across the brand, exclusive of GST and other incidentals such as insurance. If face-to-face consultations are required, the cost to the brand will increase to \$108,000 per week. This is solely the costs associated with the provision of the physician in clinic and doesn't cover other outlays incurred by the clinic as a result of additional staff.

The additional cost would need to be, in whole or in part:

1. Passed onto the consumer; or
2. Absorbed by the clinic, all of which are small business and unable to meet these costs.

Consequently, the additional operating expenses will likely cause:

1. Staff reductions as:
 - (a) The inclusion of a face-to-face consultation by a physician may cause our registered nurses to become redundant as the price of the injectables services and the size of

¹¹ <http://www.nzscm.co.nz/media>

the clinics does not allow for an additional staff member/Doctor to complete the service. If larger rooms are required to accommodate the presence of a Nurse and Doctor, this will lead to increased rent and operating expenses; and

- (b) The increased operating cost of the clinic to allow for an on-site Doctor may mean that staff costs for the provision of other services within the clinic may need to be reduced, and
2. Increased insurance costs across all clinics due to the presence of a Doctor on-site.

12. LASER TREATMENTS

Currently, the operation of lasers in our Queensland businesses are strictly governed by Radiation Health. Queensland currently maintains some of the highest safety standards across the country. Despite these regulations only applying to our Queensland clinics, all of the clinics across the Australian Skin Clinics brand, whether located in Queensland, Victoria or New South Wales, operate in accordance with the safety standards and training requirements imposed by Radiation Health Queensland.

There are a number of factors that influence the effectiveness and safety of laser treatments, including by not limited to:

1. Medications currently being taken by the consumer at the time of the treatment (and in the weeks leading up to the treatment);
2. Sun exposure to the area to be treated in the two weeks before and after the treatment;
3. Whether the hair is unshaven, plucked or waxed in the two weeks leading up to the treatment;
4. Tattoos or permanent makeup in the treatment area;
5. The use of Retinol A or hydroquinone in the three days prior to treatment;
6. Presence of an active bacteria or viral infection;
7. History of scarring or keloid formation;
8. Psoriasis or vitiligo
9. Pregnancy and breastfeeding.

If a cooling off period applied to the provision of laser treatments, it is highly probable that one of the above factors may change across the course of the cooling off period, meaning that a new consultation would need to be undertaken before the treatment is conducted.

For the safety of the consumer, Australian Skin Clinics considers that it is always best to accurately assess the skin within the area to be treated on the actual day of the treatment, to ensure assess the suitability of the treatment at that time, after an assessment of the above factors are taken into consideration.

On that basis, we do not think that it is suitable for a cooling off period should apply to laser or other minor non-surgical treatments. In Australian Skin Clinics' view, we consider that Radiation Health sets an acceptable standard for how lasers should be operated and how laser technicians should be trained, to ensure that safety of consumers.

13. REPOSE TO QUESTIONS AND RECOMMENDATIONS

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?**

We feel that this question falls outside the scope of Australian Skin Clinics business model and relates to treatments and procedures that are not classified as minor non-surgical treatments.

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?**

We feel that this question falls outside the scope of Australian Skin Clinics business model and relates to treatments and procedures that are not classified as minor non-surgical treatments.

We feel that we discharge our duty in providing extensive information to our consumers about our minor non-surgical treatments by way of information on our website, pre and post care flyers, face-to-face discussions with our Registered Nurses or Nurse Practitioners within the clinic and the during the telemedicine consultation with our Doctors.

Further, given that our minor non-surgical procedures utilise only non-permanent injectable products, the result of making a rushed decision is not of significant concern, given that the effects will naturally dissipate over time, and will filler can be dissolved with hyaluronidase.

3. **Is there evidence that consumers cannot access reliable information or are relying on inaccurate information when making decisions about these procedures?**

Australian Skin Clinics only publishes information about our minor non-surgical treatments in accordance with all applicable legislation in conjunctive with the:

- (a) Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*;
- (b) Australian Health Practitioner Regulation Agency, *Guidelines for Advertising Regulated Health Services*;
- (c) Australian Competition and Consumer Commission, *Fair treatment: Guide to the Trade Practices act for the advertising or promotion of medical and health services*;
- (d) Medical Board of Australia, *Guidelines for advertising of regulated health services*; and
- (e) Australian Government, Department of Health and Ageing Therapeutic Goods Administration, *Therapeutic Goods Advertising Code*.

4. Is there evidence that inappropriate use of qualifications and titles by medical practitioners may be misleading to consumers?

We feel that this question falls outside the scope of Australian Skin Clinics business model and relates to treatments and procedures that are not classified as minor non-surgical treatments.

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?

Australian Skin Clinics does not actively offer finance for our minor non-surgical treatments. This is because the treatments at Australian Skin Clinics do not meet the minimal threshold for credit approval.

6. Is there other evidence of disproportionate numbers of complaints or adverse events for consumers who have had these procedures?

As discussed earlier in our submission, from the six months between 1 July 2014 to 31 December 2014, 100,000 treatments were conducted across the brand. Adverse events recorded for this same period occurred in 0.2% of treatments. We feel that the number of adverse events is low, given the number of treatments conducted. Adverse events whereby an undesirable outcome was experienced for injectables was 0.172% of total injectable treatments for that period. This includes events such as bruising or swelling.

The largest portion of adverse events is client expectation. In many instances client expectations can be rectified with further treatment. In others where such action is not possible, the client understands that the product is not permanent and will dissipate over time.

Further the Therapeutic Goods Association (TGA) has recorded only 109 adverse drug reactions in Australia in the last twenty years for the two most common anti-wrinkle injections used in Australia – Dysport and Botox. By comparison, Paracetamol has recorded 809 adverse drug reactions listed and over 60 deaths for the same period. In 20 years there has been no deaths by cosmetic injectables.

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?

We feel that this question falls outside the scope of Australian Skin Clinics business model and relates to treatments and procedures that are not classified as minor non-surgical treatments.

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?

We feel that this question falls outside the scope of Australian Skin Clinics business model and relates to treatments and procedures that are not classified as minor non-surgical treatments.

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.

In relation to the Board's questions:

9. Does the Board's current code of conduct and the existing codes and guidelines of the professional bodies provide adequate guidance to the medical practitioners providing cosmetic and surgical procedures?

In relation to Nurse Injectors or Doctors that are actively seeking to do cosmetic injectables, we consider that there is scope for mandatory theoretical and practical experience be undertaken before they conduct this type of procedure.

It is important to note that we do not feel that the courses currently available in Australia as suitable for the purposed of training Doctors and Nurses on cosmetic injectables. We would welcome discussion surrounding what a suitable course would be for cosmetic injectables taking into consideration suitable practical and theoretical training, affordability for practitioners and length of course.

10. How effective are existing professional codes and guidelines in addressing the problem identified by the Board?

We do consider that the status quo be maintained with respect to the provision of a telemedicine consultation prior to the procedure being conducted. We currently utilise the current guidelines from the Medical Board of Australia for Technology-based consultations adequately ensures that the standard of care offered through telemedicine is of a standard equal to that offered during a face-to-face consultation. Our client's care and safety is paramount.

11. Do you agree with the costs and benefits associated with retained the status quo as identified by the Board?

The costs and benefits listed in the scenario provided does not relate to minor non-surgical treatments offered by Australian Skin Clinics.

12. Are there other costs and benefits associated with retaining the status quo that the Board has not identified?

The costs and benefits of maintaining the status quo in relation to telemedicine consultations and supporting our small business operators in outlined in our submission above.

Option 2

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

In relation to the Board's 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?

Comprehensive educational material is essential in our Doctors and Nurses discharging their duty of informed consent. At Australian Skin Clinics, we take this duty very seriously and provide extensive information to our consumers about our minor non-surgical treatments by way of information on our website, pre and post care flyers, face-to-face discussions with our Registered Nurses or Nurse Practitioners within the clinic and the during the telemedicine consultation with our Doctors. We further provide post care education with a follow up within a 24 hour time frame and then a client review within two weeks.

14. Who do you think is best placed to design consumer education material about cosmetic medical and surgical procedures provided by medical practitioners?

We consider that there is currently adequate legislation and guidelines regarding the provision of consumer education material (as outlined in question 3) to allow business to design consumer education material suitable for its consumers.

15. Who should pay for the development of consumer education material?

We consider that it should be the responsibility of the relevant business to ensure that it develops education material in accordance with current legislative and regulatory standards.

16. Are there any other costs and benefits associated with providing consumer education material that the Board has not identified?

The highest proportion of adverse events at Australian Skin Clinics relate to client expectation. The provision of consumer education material will aid the industry in managing client expectation.

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.

In relation to the Board's questions:

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

17.1 Should there be mandatory cooling off period for adults considering a cosmetic medical or surgical procedure (other than for minor procedures)?

This questions falls outside of the scope of Australian Skin Clinics business model and so is outside the scope of our submission.

For many of Australian Skin Clinic's minor non-surgical treatments, a cooling off period could actually do harm for a client. For example if a client has a laser hair consultation and then returns in 7 days and has had sun exposure or is now on medication, there can be risk to having a treatment and potential harm caused.

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?

This questions falls outside of the scope of Australian Skin Clinics business model and so is outside the scope of our submission.

Australian Skin Clinics do not treat under 18 persons for cosmetic injectables.

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?

We do consider that our Doctors do take these issues into consideration when completing the telemedicine consultation. In the training material for all staff (including our Doctors and Nurses) we include information of identifying underlying psychological problems and all staff are actively encouraged in raising the possibility of any patient's possible psychological problems with our Doctor, for proper assessment.

If the Doctor diagnoses that the client has possible psychological problems, our policy is to not treat that client.

17.4 Should medical practitioners be expect to refer these patients to an independent psychologist or psychiatrist for evaluation?

The safety and care of our consumers is paramount. If our Doctor's consider that this is the most suitable course of action for the client, then Australian Skin Clinics fully supports our Doctor's decision to refer that client 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)?

This questions falls outside of the scope of Australian Skin Clinics business model and so is outside the scope of our submission.

17.6 Should there be further restrictions for patients under the age of 18 who seek cosmetic medical and surgical procedures?

This questions falls outside of the scope of Australian Skin Clinics business model and so is outside the scope of our submission.

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?

No. At Australian Skin Clinics, we believe that our Doctors discharge their duty of care to the client during the telemedicine consultation. We believe that the shared care between a Doctor and a Nurse is acceptable for cosmetic injectables, particularly as injectables are elective procedures and in terms of the products available within our clinics, not permanent.

We do believe that with the extensive training and practical experience offered to our Nurses, that our Nurses provide exceptional specialised service. Our Nurses are solely focused on providing the best injectables treatments within the market.

We also believe that Australia, like the United State of America and New Zealand, should be at the forefront of innovation in medical care and should allow Doctors to conduct consultations by way of telemedicine consultations, so that more Doctors can focus on more complex health needs within the community.

18. Are there other elements not included in the draft guidelines at Attachment B that could be included?

Under the section relating to Training and Experience, there is scope for mandatory training for Doctors and Nurses who want to conduct cosmetic injectables, to ensure that there is quality control within the industry.

19. Do you agree with the costs and benefits associated with guidelines with explicit guidance (option 3) as identified by the Board?

No. The costs and benefits set out in the guidelines does not cover the implications to the industry, if there is a change in the status quo of Doctors providing a face-to-face consultation for cosmetic injectables.

The impact of this change on small business would need to be fully assessed, in light of the Australian Competition and Consumer Commission's final report on competition.

20. Are there other costs and benefits associated with guidelines with explicit guidance (option 3) that the Board has not identified?

Yes. The full economic impact of these changes would need to be assessed and we consider that the Australian Competition and Consumer Commission may be able to provide guidance on this issue.

21. Would the benefits of guidelines with explicit guidance (option 3) outweigh the costs, or vice versa?

Australian Skin Clinics' submission solely relates to minor non-surgical treatments. Given the number of adverse events that have arisen in our clinics over the six month period as outlined above, we do not feel that the introduction of face-to-face consultations for all cosmetic injectable treatments would provide a benefit to consumers that outweighs the costs of introducing this requirement.

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.

In relation to the Board's questions:

22. Do you agree with the costs and benefits associated with guidelines which are less explicit (option 4) as identified by the Board?

The costs and benefits listed in Option 4 do not relate to minor non-surgical procedures and on that basis, Australian Skin Clinics' is not submitting on this point.

23. Are there other costs and benefits associated with guidelines which are less explicit (option 4) that the Board has not identified?

The costs and benefits listed in Option 4 do not relate to minor non-surgical procedures and on that basis, Australian Skin Clinics' is not submitting on this point.

24. Would the benefits of guidelines which are less explicit (option 4) outweigh the costs, or vice versa?

The costs and benefits listed in Option 4 do not relate to minor non-surgical procedures and on that basis, Australian Skin Clinics' is not submitting on this point.

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

The Board should consider the preliminary information provided in Australian Skin Clinics' submission, relating to the impact of face-to-face consultations on our small business operators. We believe that more research would need to be conducted to fully assess the implications on cost to our businesses and the consumer if these changes were implemented.

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

Australian Skin Clinics would like to see the standard for Doctors and Nurses providing cosmetic injectables, to be in line with the standard set for our brand. We encourage an invitation to participate in a more in-depth review of the minor non-surgical procedures and setting some guidelines and regulations to lift the standard of service delivery in the industry to maintain the integrity and quality of these services and ensure consumers are protected and well cared for in a consistently high manner.

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

The position of Australian Skin Clinics, in relation to minor non-surgical treatments is a hybrid of the options offered as follows:

- (a) Maintain the status quo with respect to the telemedicine consultation for cosmetic injectables;
- (b) Introduce mandatory training for Doctors and Nurses who provide cosmetic injectables;
- (c) Encourage providers to increase the level of consumer information so that consumers are aware of the range of anticipated outcomes as a result of cosmetic injectable treatments;
- (d) Encourage providers to publish details of their training and experience to ensure that consumers do not consider illegal backyard operators or online cosmetic injectables.

14. CONCLUSION

Whilst the *Public Consultation - Registered medical practitioners who provide medical and surgical procedures* was not strongly focused on minor non-surgical procedures, Australian Skin Clinics felt it important to highlight the areas in which this sector of the industry can be strengthened.

Education and Training

Australian Skin Clinic believes that there is an opportunity to support this growing industry with targeted and tailored programs for Doctors and Nurses wishing to train in the administering of cosmetic injectables. We believe that the training programs available in the marketplace currently are not in-depth enough to support the education and learning of Doctors and Nurses in this area. In particular, we feel that a certificate course should be developed with greater practical training components.

Telemedicine consultations utilised for the provision of cosmetic injectables

Australian Skin Clinics believes that telemedicine is a safe and effective way to provide Nurses access to a skilled and capable Doctor, who can provide supervision in the administering of cosmetic injectables. The manner in which Australian Skin Clinics uses this technology is highly structured with strict guidelines and protocols to ensure ultimate client care and safety.

Telemedicine is auditable and easily compliance checked.

It is our opinion that the use of telemedicine does not diminish the result for the consumer, nor add additional risk to safety. Telemedicine has been shown to be a safe and effective way to deliver a wide range of services in the medical industry, utilising the skill of Nurses. It is a method widely accepted in other countries such as the United States of America, Canada and New Zealand. We believe that Australia is a leader in the provision of medical services and should meet the standards of these international counterparts.

Cooling off period for other minor non-surgical treatments

It is the view of Australian Skin Clinics that Radiation Health Queensland sets an acceptable standard for how lasers should be operated and how laser technicians should be trained, to ensure safety of consumers. This is a benchmark we enforce across all of our clinics regardless of location. We do not think that it is suitable for a cooling off period should apply to laser or other minor non-surgical treatments.

If a cooling off period applied to the provision of laser treatments, it is highly probable that lifestyle factors such as sun exposure and use of medications may change across the course of the cooling off period, meaning that a new consultation would need to be undertaken before the treatment is conducted.

For the safety of the consumer, Australian Skin Clinics considers that it is always best to accurately assess the skin within the area to be treated on the actual day of the treatment.