Introduction

What is your name?

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What is your email address?

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Does your feedback represent an individual or group / organisational perspective?

A group / organisational perspective: The Cosmetic Physicians College of Australasia and the Cosmetic Physicians Society of Australasia (CPCA)

What is your role?

President Cosmetic Physicians College of Australasia and President Cosmetic Physicians Society of Australasia

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Professional Authority

Will the proposed regulations address the identified issues?

Unsure

Other comments:
The CPCA believes that the proposed regulatory changes in relation to professional authority do have the potential to address the identified issues. However, the regulations will need to address current prescribing rights for nurse practitioners and the current lack of definition around scope of practice for dentists in greater detail for this to be achieved.

The CPCA's response relates specifically to the Schedule 4 poisons botulinum toxin and dermal fillers. The administrations of botulinum toxin, also known as Botox, and dermal fillers are classified as minimally invasive procedures and the substances are classified Schedule 4 medicines.

The Therapeutic Goods Administration's (TGA's) Australian Public Assessment Report (AusPAR) states that current use of Botox includes blepharospasm; strabismus; focal spasticity in adults and children two years and older; cervical dystonia (spasmodic torticollis); primary hyperhidrosis of the axillae; spasmodic dysphonia; and decreasing the severity of glabellar lines, crow's feet and forehead lines. The CPCA notes that all of the conditions listed require a medical practitioner's diagnosis and would be classified as either skin or musculoskeletal conditions.

Further, in relation to Botox's important role in assisting with the musculoskeletal system, the Australian Government recently included Botox on the Pharmaceutical Benefits Scheme (PBS) with prescriber rights limited to medical practitioners only. This move reflects the complexities and high standard required for prescribing Botox to patients, particularly those with complex needs.

Cosmetic medicine procedures require an understanding of complex facial anatomy, regional anatomy and intimate knowledge of the medicine used and its placement within a patient. Therefore, prior to the administration of Schedule 4 medicines, the patient should undergo a medical history and face-to-face examination by the treating medical practitioner. The use of fillers is three dimensional; routine use of video conferencing technologies is not acceptable when prescribing these products. Once the treating doctor has undertaken a consultation and the patient is deemed psychologically and physically suitable for treatment, then a treatment plan can be arranged.

The worth of these measures is demonstrated by well-documented cases where the use or misplacement of these medications has caused issues such as intra-arterial injection leading to blindness, lip and skin necrosis, chronic granulomatous reactions causing chronic pain and/or disfigurement, drooping eyelids or, equally seriously, deep dermal infections and associated morbidities. The reality is that as injectable dermal filler technology is becoming more advanced, the fillers are now longer-lasting, and misplaced fillers have the potential to significantly impact on a patient's wellbeing for a longer period of time.

Individuals who do not have the required level of training and ability to manage risks, such as acute or chronic infections or accidental intravascular injection needlessly expose their patients to adverse medical outcomes. It is this risk to patients that the CPCA believes needs to be carefully considered when reviewing regulations concerning the below two areas.

Prescribing rights for nurse practitioners

Under the current regulations, nurse practitioners with a notation in perioperative care are allowed to prescribe Botox and dermal fillers. This is contrary to other jurisdictions where a nurse practitioner is only delegated administration rights. Botox and dermal fillers are not used or associated with perioperative care but instead are commonly used for the treatment of aesthetic and musculoskeletal conditions. Therefore, there is no immediate or urgent requirement for a nurse involved in perioperative care to have prescribing rights for such medicines.

What is now occurring is that some nurses are gaining perioperative care qualifications specifically with a view to exploiting the loophole in the regulations by setting up cosmetic clinics and employing other nurses to administer Botox and filler injections, all without the initial medical practitioner assessment that is normally required for the administration of a Schedule 4 medicine.

Cosmetic medicine is a rapidly expanding and changing field which requires constant updating of skills and education. It is to provide this focus on skills and education that the CPCA exists. The CPCA believes that it is necessary to holistically treat cosmetic problems caused by excessive exposure to UV radiation, which are very prevalent in Australia. As such it is inappropriate to treat rhydites

(wrinkles) in isolation from consideration of other photodamage of exposed skin, including but not limited to skin cancers.

Dentists operating outside of their scope of practice

The current powers given to the Dental Board of Australia do not allow for the Board to determine what activities count as "dental treatment", so while it is possible to say a dentist can only prescribe for the purpose of dental treatment, without a definition of what counts as dental treatment a dentist is free to argue that any procedure they perform is in some way a dental procedure.

This is of particular concern to the CPCA because an increasing number of dentists in Australia are using Schedule 4 medicines, specifically cosmetic injections, to perform cosmetic medical procedures.

Cosmetic injections can be used by dental practitioners to treat temporomandibular joint disorder/dysfunction, which is why it is appropriate that dentists are able to prescribe this medicine, even though use in this area is off-label. However, the use of cosmetic injections for treatments unrelated to dentistry such as, but not limited to, glabellar (frown) lines, crow's feet and forehead lines, and the management of any complications, requires a much broader knowledge of cosmetic medicine.

It is appropriate therefore, that medical procedures involving the use of cosmetic injections be performed by, or under the supervision of, only those medical professionals trained specifically in this field after a face-to-face consultation with the supervising doctor.

By failing to define what constitutes dental practice, the current legislative framework leaves no option for the Dental Board of Australia but to stand aside while dentists perform cosmetic medical procedures for which they are not qualified. That said, there is a clause in the legislation which limits the performance of dental procedures to dentists. This means that while a medical practitioner cannot perform a dental procedure – which is entirely as it should be, as medical practitioners do not have the intimate knowledge of the dental structure required to perform those procedures – dentists are free to perform medical procedures despite not having the required background medical training. This is obviously an absurd situation, but one which can be easily rectified by providing a clear definition for the scope of dental practice. For example, the definition of the scope of dental practice could be "the treatment of the teeth and the processes of mastication and their disease states only".

This defining of the scope of practice would undoubtedly be useful in other areas of practice as well, so that medical treatments are proscribed for those without medical qualifications, as dentistry is proscribed for those without dentistry qualifications.

Are there other impacts of the proposed regulations that should be considered?

As described above, the impact of the proposed regulations could be to provide clear guidance about medical procedures which involve Schedule 4 medicines and the importance of those being performed only by medical professionals. The result of this would be better protection for the public, so that patients can be sure that the professionals offering services have the necessary background knowledge and training.

Structured prescribing arrangements

Will the proposed regulations address the identified issues?

Unsure

Other comments:
The CPCA very much supports the proposals to provide a single regulatory framework for structured prescribing arrangements. We also believe that setting clear regulatory guidelines regarding minimum requirements for a structured prescribing arrangement is necessary.

However, we have some concern about setting too broad a scope for the use of structured prescribing arrangements. We believe that such arrangements are important as they allow access to necessary medical treatments where availability of medical services is limited or where there is an urgent need. We believe that structured prescribing arrangements should be limited to these kind of situations and not be allowed for treatments and procedures which are not medically-imperative, such as the cosmetic medical procedures provided by our members. We do not believe that there is a justification for cosmetic medical treatments involving Schedule 4 medications to be prescribed without an in-person, face-to-face consultation with a medical doctor. This face-to-face consultation is necessary so that the doctor can make judgements about a patient's skin condition, the best types of treatments, any potential complications, whether there are any indicators of undiagnosed medical conditions, such as melanoma, and the patient's psychological state and motivations for treatment.

While we believe that current arrangements do preclude treatments such as cosmetic medical treatments from being included in a structured prescribing arrangement, we know that this has been interpreted differently by other professionals. We therefore believe that a clear line in the regulation would improve the application of these arrangements and limit them to the situations for which they were developed.

Again, there may be other areas of practice which should not be included in the permissions for structured prescribing arrangements and we believe that a requirement for the treatment to be medically-necessary and urgent would cover these situations.

In addition, the CPCA has some concerns about including all types of medications from the Schedule 4 list in the allowances for structured prescribing arrangements. We believe that there are many medications for which there isn't likely to be an urgent medical need and that these medications should not be included in the framework for structured prescribing arrangements. With this in mind,

we would propose an opt-in system for Schedule 4 medications, with items added to the framework on a case-by-case basis. This ensures that only those medications which might be needed in an urgent medical situation can be included in a structured prescription arrangement and reduces the risk of over-application of the arrangements when potentially harmful treatments are involved.

Are there other impacts of the proposed regulations that should be considered?

As noted above, the impact of the proposed regulations could be to improve the application of the arrangements by limiting them to medically-imperative treatments, if restriction were included in the framework. If such restrictions are not included in the framework, the proposed regulatory changes could set a precedent which encourages the use of structured prescribing arrangements to be used in a wider range of situations, unnecessarily putting patient safety at risk.