CHINESE MEDICINE AND ACUPUNCTURE SOCIETY OF AUSTRALIA'S
SUBMISSION TO MEDICINE BOARD OF AUSTRALIA, APRIL 2019

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RE: Medical Board of Australia Public Discussion Paper February 2019:

"Options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments".

Dear Sir/Madam

The **Chinese Medicine and Acupuncture Society of Australia**, **CMASA**, wishes to extend its appreciation for the opportunity to comment on the Discussion Paper, particularly from the perspective of intersectional issues between medical practice and other forms of **AHPRA** regulated health services.

The CMASA is a professional association representing the interests of APHRA accredited Acupuncturists, Chinese medicine practitioners and Chinese Medicine dispensers, who come under the regulatory control of the **Chinese Medicine Board of Australia**, **CMBA**. Some of its members are both acupuncturists and medical practitioners, and as such, fall under the regulatory control of both the CMBA and the MBA.

CMASA supports the objectives of the paper in providing clarity for medical practitioners within an ever evolving area of health service provision and broadening public expectations, the setting of safety standards for the protection of patients and ensuring the accountability mechanisms support medical practitioners across all aspects of their health service provision.

CMASA supports the MBA's contention that there is a need for greater engagement with the practices of medical practitioners who are involved in experimental treatments which may or may not deliver benefits to patients and the wider community (e.g. Lymes disease, stem cell therapy), are implementing community asserted experiential treatments (e.g. cannabis use for the treatment of childhood epilepsy or endometriosis), are working at the cutting edge of technological treatments (such as stem cell therapy for cosmetic surgery), and as well as for those who are applying non-medical techniques such as acupuncture or dry needling in their medical practice.

CMASA is concerned that the paper is attempting to move forward on these issues without addressing the regulatory framework provided by AHPRA under the National Law, and as such, its recommendations will further confuse the situation rather than clarify it, and leave the current regulatory gaps in place which are contributing to the current problem. Most significantly, its approach will enable medical practitioners undertaking 'emerging/experimental' treatments, to remain outside of the accountability frameworks established by AHPRA boards.

A more practical approach would be for MBA to focus more on regulatory areas of responsibility under AHPRA rather than trying to tease out definitions, which are often outdated and not aligned to current health service provision. As a starting point, it should separate out health service delivery that reasonably falls within the MBA's regulatory scope under the National Law (including various emerging services), from services that are regulated by another AHPRA Board, such as the CMBA for acupuncture services. In establishing what reasonably falls within the sphere of medical practice, the Board should look to the skills and expertise required to plan and deliver the technique/service, and consider whether or not the practice falls within the ambit of another AHPRA Board.

CMASA contends there is a regulatory gap on intersectional areas for medical practitioners who in addition to medical services, deliver health services regulated by other AHPRA boards. This gap result in the current situation of uncontrolled service provision by medical practitioners with no accountability, and where poorly delivered, damages the reputation of qualified Acupuncturists. It can also discourage patients from seeking acupuncture treatment that would benefit them.

CMASA wishes to make it clear that it is not opposing to medical practitioners in providing acupuncture services, and indeed, some of our members are registered as both medical practitioners and acupuncturists, and as such, demonstrate the way that a health service practitioner can fall under the two regulatory Boards.

CMASA believes that the MBA, in order to meet its regulatory obligations under the National Law/AHPRA framework, needs to separate out:

- Health practices that fall under the MBA's domain, being medical practices (albeit needing to be categorised into subgroupings such as 'approved'/'being monitored'/'prohibited' practices). This would provide a framework within which to deal with emerging or developmental treatments that require the skills of a qualified medical practitioner and that are not regulated by another Board, foster innovation while still providing oversight and bringing service provision under the regulatory control of the Board. It also provides a pathway for the eventual smooth transitioning of a treatment from 'being monitored' status to 'approved' or 'prohibited', and
- Health practices that fall outside the MBA's regulatory domain, in that they are regulated by another AHPRA Board (such as Chinese Medicine), as well as from health services not regulated by AHPRA, which constitute 'unregulated health services'.

Thus, the regulatory controls proposed in Option 2 would need to be expanded, with MBA to provide for:

- The development of a framework within which it is more actively monitors emerging/developmental treatments (e.g. impose reporting obligations on practitioners) so that the MBA can keep up to date with the outcomes/risks and inform both medical practitioners and the public, particularly to hold them to account in order to protect the public. It is noted that Option 2 only requires documentation in the patient record, so that the problems in high risk areas of practice are likely to continue to go unobserved until a serious injury or death results in an investigation
- the development of a mechanism to ensure that medical practitioners who provide any health service regulated by another AHPRA board meet the regulatory requirements set by the relevant AHPRA Board, and
- The establishment of clearer reporting requirements to MBA on unregulated health service provision by medical practitioners, and a clear mechanism for the reporting of adverse events arising from unregulated health services. Without this, medical practice is likely to remain uninformed of emerging problems.

On this basis, Option 2 needs to be amended to include emerging/experimental practices, such as stem cell therapy or medicinal cannabis treatment, as high-risk medical practices which come under the regulatory controls of the MBA, rather than pushing them aside to form part of an unregulated area of health service provision. If MBA fails to provide necessary oversight, CMASA considers it fails to meet its obligations under section 41 of the National Law to define what is appropriate professional conduct or practice for the profession, to keep the public safe. Closer engagement by MBA would provide for the early identification of red flags (and promotion of productive discussion around such), and could also contribute to greater awareness of innovative practices.

For AHPRA regulated health services which are not medical services, Option 2's guidelines need to be amended to recognise the need for medical practitioners to meet the standards set by the relevant AHPRA Board, and MBA would need to liaise with each Board to ensure that a mechanism is put in place for the development of relevant requirements:

- qualification requirements for medical practitioners, recognising prior learning but ensuring key learning attributes for TCM are met, particularly the theoretical basis for delivering treatment, as well as the specification of accreditation requirements for training providers.
- For acupuncture services, the CMBA has the expertise and systems appropriate for closing off this current gap. It is noted that while evidentiary data is very limited, acupuncturists indicate that patient often report that have been treated by medical practitioner with acupuncture/dry needling, have found the treatment to be ineffectual, even though delivered over an extended period of time. Medical practitioners are applying acupuncture to patients after undertaking very short training courses (2 days/2 weeks), obtaining training from providers with no CMBA approval or accreditation, and use of techniques outside of the theoretical framework in which they are supposed to be delivered, and without any accountability for results.

MBA would need to work jointly with CMBA and could update current standards to require medical practitioners to meet CMBA requirements, or joint MBA/CMBA requirements. This

would require section 2.4 of the proposed Guidelines to be amended to replace "appropriate training, expertise and experience" and "necessary training" with the requirement for practitioners to meet the requirements set out by the relevant regulatory Board. If MBA proceeds with the current wording in Option 2, it needs to ensure that it provides for patients to be informed that the level of training is less than that required by CMBA.

For health services that are not regulated by an AHPRA Board, to provide for public safety, MBA may need to provide a mechanism for greater transparency about the level of training and experience that constitutes "appropriate", particularly as a guide for any disciplinary processes, and ensure that the accountability mechanisms (complaints systems, adverse event reporting) reflect such. The MBA needs to meet the information needs of the public, in terms of what they should expect from medical practitioners when they provide an unregulated health service, as well as any other AHPRA regulated health service.

CMASA also sees the need for changes to suggested terminology used so as to provide a clearer indication of the different types of health services being discussed and to better reflect the current regulatory framework. The term 'conventional medicine' is now confusing as the scope of regulated services was broadened by the National Law's regulation of various types of health services.

Greater precision of meaning would be provided by the use of functional terms, so that 'medical practice/services' should replace 'conventional medicine', 'Allied Health services' should replace 'complementary and .. services' to collectively cover all other AHPRA regulated health services, and 'unregulated health services' should be used to cover those services that fall outside of the AHPRA regulatory framework (but excluding emerging/experimental services that are medical services).

CMASA is thus opposed to the proposed use of the terms 'conventional medicine/unconventional medicine' and 'complementary medicine', as they no longer fit the AHPRA service delivery framework. Additionally, the term 'conventional medicine' is imprecise and could be problematic for Hearing processes. For example, A tribunal may need to begin a hearing by determining whether an injury to a patient (such as may arise from inappropriate bloodletting on acupuncture points), constitutes:

- a conventional form of conventional medicine (conventional conventional technique)
- an unconventional form of conventional medicine (unconventional conventional technique)
- a conventional form of an unconventional medicine, (conventional unconventional technique) or
- an unconventional form of an unconventional medicine (unconventional unconventional technique).

The substitution of 'medical practice' and 'Allied health service' (or in this example, of Acupuncture practice) would give much greater clarity to the issue at the centre of the Hearing, and once it was established that the treatment technique was an Allied Health Service treatment, could be reviewed against the standards set by the appropriate Board.

The inclusion of 'emerging treatments' with Allied Health Services and unregulated services is not useful in that it fails to provide the necessary protections the public would reasonably expect from a

medical practitioner. It does not provide a mechanism for redress by injured patients (physically, mentally, financially) through such processes.

In summary, while CMASA supports the objectives of the report, it believes the strategies outlined in Option 2, while going part way, do little more than entrench the status quo (Option 1) and need to be reframed to reflect the AHPRA regulatory framework. CMASA is particularly concerned that Option 2 fails to recognise the responsibility of the Chinese Medicine Board in setting the standards for the delivery of Chinese Medicine services, so that acupuncture services provided by medical practitioners fall outside of the quality assurance framework provided by CMBA, and are not supported by an alternate quality framework.

Responses to the specific questions outlined in the report are attached.

Please do not hesitate to contact me for further clarification.

Yours sincerely

CMASA Office

CMASA RESPONSES TO SPECIFIC QUESTIONS

1. **Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'? If not, what terms should be used and how should it be defined?**

ANSWER

CMASA strongly disagrees with these terms and considers MBA should use terms that more precisely describe the type of services being delivered, and that reflect the AHPRA regulatory framework providing for their delivery. This could be used by using terms such as 'Medical practice', 'Allied Health Services' and 'unregulated health services', where:

- **Medical practice**, with the scope of services broken into 3 subcategories of
    - "Approved" (currently approved set of protocols)
    - "Monitored" (treatment protocols not falling within the currently approved set, including those undergoing clinical trials as well as a higher risk category of treatment practices referred to in the paper as 'emerging services') and
    - "Prohibited" (treatment protocols assessed by the MBA as unacceptable).

- **Allied Health services** as the collective term for all types of Health Services that are not medical services but which are regulated by AHPRA, such as Chinese Medicine (including Acupuncture, Chinese herbal medicine and Chinese herbal dispensing)

- **Unregulated Health services**: all health services which are not regulated by AHPRA, and which exclude the services indicated in the paper as 'Emerging services'.

2. **Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine., whether used in additional to, or instead of conventional medicine. This includes unconventional use of approved medical devices and therapies'. If not, how should it be defined?**

ANSWER

While the scope of practices included in the definition is comprehensive (assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment), it is a generic grouping and is applicable to all health service provision.

CMASA does not consider it useful to combine 'complementary and unconventional and emerging treatments' together, without regard for the regulatory framework within which they delivered. The AHPRA regulatory framework (under the National Law) needs to be built into the approach as it is that which provides the public with guaranteed levels of safety and accountability.

Not only is this approach inconsistent with the AHPRA regulatory framework, but it fails to provide the clarity needed for enforcement action by investigative bodies or Tribunals. The term 'conventional' is 'value laden' rather than functional, so that explanations like "not usually

considered to be part of conventional medicine" fail to provide any clarity to practitioners or their oversighting bodies. These terms should be replaced with those outlined in the response to Q1.

3. **Do you agree with the nature and extent of issues identified in relation to medical practitioners who provide 'complementary and unconventional and emerging treatments'?**

ANSWER

Recent Australian reviews into Ageing, Disability and Institutional Sexual Abuse have demonstrated that relative few complaints reach the level of formal hearings, and that there remains a serious level of injury to individuals that goes unreported, unacknowledged and untreated. It is expected that there is a serious underreporting of problems and poor service.

The paper does not refer to any complaints made about Allied Health service provision by medical practitioners but CMASA practitioners often comment that their patients report that they have been treated with acupuncture by a medical practitioner, but that this has been ineffective, and often with prolonged treatment. Medical Practitioners appear to be practising acupuncture after undertaking courses over 2 – 14 days from uncertified training organisations, in contrast to the CMBA requirement for qualified acupuncturists to complete a 4 year fulltime tertiary course.

4. **Are there other concerns with the practice of complementary and unconventional medicine and emerging treatments by medical practitioners that the Board has not identified?**

ANSWER

The public would reasonably assume that all services provided by medical practitioners meet the requisite standards of care in accordance with the broader AHPRA regulatory framework. They are unlikely to be aware that the delivery of health services such as acupuncture by medical practitioners is effectively unregulated and not to the standard required by the relevant AHPRA board, the CMBA.

5. **Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'? (delivered by medical practitioners)**

ANSWER

Yes, safeguards are needed. All services provided by medical practitioners should be delivered in accordance with regulated standards and the information should be made clearly available to patients/the public, particularly about what standards they can expect a medical practitioner to meet in delivering non-medical health services. Where a medical practitioner provides an Allied Health Service, it should be done so in a way that meets the regulatory requirements of the relevant AHPRA board. Where it involves an untested medical practice delivered by a medical practitioner,

the MBA should provide a close monitoring framework within which any such services must be delivered, documented and evaluated. This includes information to patients.

6. **Is there other evidence and data available that could help the Board's proposals?**

ANSWER

To keep abreast of treatments being used by members of the public which (if to be validated through clinical trials and approved would come within the ambit of medical services) MBA may need to consider setting up a mechanism for obtaining informal advice from representative organisations. Allied Health Service providers (and their representative bodies) could also be encouraged to use this mechanism to draw attention to areas MBA needs to exert quality controls over.

7. **In the current regulation (i.e. the Board's Good medical practice) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?**

ANSWER

No.

8. **Would guidelines for medical practitioners issued by the Medical Board (option two) address the issues identified in this area of medicine?**

ANSWER

No, Option two partially addressed the need, but fails to provide for a mechanism to close the current regulatory gap for medical practitioners providing services regulated by other AHPRA boards. It also fails to provide an adequate framework for 'emerging treatments' delivered by medical practitioners, which need to fall within the regulatory ambit of the MBA.

9. **The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended: Is there additional guidance that should be included?**

ANSWER

The guidelines should direct medical practitioners wanting to provide services regulated by other AHPRA Boards, such as CMBA, to those Boards, in order to qualify for competency, and to come under the relevant accountability mechanisms.

The guidelines should also address emerging treatments by medical practitioners and recognise they fall within the ambit of medical practice, albeit unproven, high risk and outside of the approved set of treatment protocols. Failure of the MBA to deal with the issue leaves patients badly exposed.

10. Are there other options for addressing concerns that the Board has not identified?

ANSWER

There is a need for CMBA (or a joint MBA/CMBA) production of standards for medical practitioners to qualify for providing acupuncture services (to cover: qualifications, training provider accreditation, experience, oversighting, accountability).

MBA should also address 'emerging treatments' within the medical practice framework, as failure to do so effectively leaves such areas as unregulated areas of practice, which may further the interests of any unscrupulous medical practitioners. It is not beneficial to the public, nor in the interests of productive innovation, to leave these practices unregulated.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

ANSWER

Option 3: Other, being a combination of some of the measures in Option 2, but framed within a greater focus on the AHPRA regulatory framework, changes to definitions (and hence the classification of emerging services to be included within medical services), recognition of AHPRA regulated health services, and the provision of new mechanisms, such as for the production of joint standards with CMBA/relevant AHPRA board for medical practitioners delivering allied health services.