



AUSTRALIAN
LAWYERS
FOR
HUMAN RIGHTS

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PO Box A147
Sydney South
NSW 1235
DX 585 Sydney

www.alhr.org.au

The Chief Executive Officer
Medical Board of Australia
GPO Box 9958
Melbourne
VICTORIA 3001

By email: medboardconsultation@ahpra.gov.au

Dear Sir/Madam

Consultation on complementary and unconventional medicine and emerging treatments

Australian Lawyers for Human Rights (**ALHR**) is grateful for the opportunity to provide this submission in relation to the Consultation, which proposes that additional regulations (the 'proposed regulations') apply to the practice by Australian medical practitioners of 'complementary and unconventional medicine and emerging treatments' (referred to in this submission as the 'three practices').

We have had the opportunity of reading the March 2019 submission to this Consultation from the Australian Integrative Medicine Association (AIMA) and the Australian Medical Association's (AMA) *Position Statement - Complementary Medicine 2018*.¹

This submission draws upon the AMA's Position Statement, the AIMA submission and also upon the article by Jonathan Cohen and Tamar Ezer, "Human rights in patient care: A theoretical and practical framework."²

ALHR

ALHR was established in 1993 and is a national association of Australian solicitors, barristers, academics, judicial officers and law students who practise and promote international human rights law in Australia. ALHR has active and engaged National, State and Territory committees and specialist thematic committees. Through advocacy, media engagement, education, networking, research and training, ALHR promotes, practices and protects universally accepted standards of human rights throughout Australia and overseas.

¹ AMA Position Statement - Complementary Medicine 2018 available at: <https://ama.com.au/position-statement/ama-position-statement-complementary-medicine-2018>

² (2013) 15 (2) *Health and Human Rights Journal*, available at <https://www.hhrjournal.org/2013/12/human-rights-in-patient-care-a-theoretical-and-practical-framework/>

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1. Introduction

Background & Summary

1.1 In this submission, for ease of discussion *complementary medicine, unconventional medicine and emerging treatments* will be referred to jointly as the ‘three practices,’ even though it is acknowledged that the treatments so described are not clearly defined in the Consultation Paper, and that there may be overlap between the content of the three practices. There are no single definitions of these separate practices in the Consultation Paper. The definition which is central to the Consultation is a joint definition of all three practices which treats them collectively without regard to any different characteristics, benefits or risk profiles. The joint definition states that:

complementary and unconventional medicine and emerging treatments include 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 addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.³

1.2 ALHR notes that the AMA defines ‘complementary medicine’ as medicine that includes:

*a wide range of products and treatments with therapeutic claims that are not presently considered to be part of conventional medicine. Complementary medicines include herbal medicines, some vitamin and mineral supplements, other nutritional supplements, homeopathic formulations, and traditional medicines such as ayurvedic medicines and traditional Chinese medicines. Complementary therapies include acupuncture, chiropractic, osteopathy, naturopathy and meditation.*⁴

1.3 In this submission, ALHR defines the concept of integrative medicine as:

*“the combination of the best modern medicine and the alternative and additional medicines for which ... modern medicine has scientific proofs and sufficient guarantees regarding their safety and efficiency.”*⁵

1.4 The right to health is fundamental because it is essential for the enjoyment of other rights.

³ Consultation Paper, p 5.

⁴ Op cit at 1.1 - 1.3.

⁵ R. Snyderman and A. Weil, “Integrative medicine: Bringing medicine back to its roots,” *Archives of Internal Medicine* 162 (2002), pp. 395–397, quoted in Emmanuel Kabengele Mpinga, Tshimungu Kandolo, Henk Verloo, Ngoyi K. Zacharie Bukonda, Ngianga-Bakwin Kandala, Philippe Chastonay, “Traditional/alternative medicines and the right to health: Key elements for a convention on global health” (2013) 15 (1) *Health and Human Rights Journal*, available at <https://www.hhrjournal.org/2013/10/traditionalalternative-medicines-and-the-right-to-health-key-elements-for-a-convention-on-global-health/fn-37->

- 1.5 ALHR notes that “The AMA recognises that evidence-based aspects of complementary medicine can be part of patient care by a medical practitioner.”⁶
- 1.6 ALHR is concerned that the proposed regulations are inconsistent with the human right to the highest attainable level of health because they may unduly limit:
- (a) the patient’s rights to health and to bodily integrity, which include the concomitant derivative rights to information as to potential treatments, to free choice and the provision of informed consent as to applicable treatments, to the observance of quality standards, to medical innovation, and to personalised treatment, as set out in the *European Charter of Patients’ Rights*;⁷ and
 - (b) the practitioner’s rights to due process and work rights.
- 1.7 The proposed regulations fail to distinguish different treatments according to risk or efficacy and include definitions that are too vague and general to form the basis of additional obligations or disciplinary processes. The proposed regulations risk discouraging innovation and reducing treatment choice. ALHR believes that using a human rights framework to test the issues to be considered by the Consultation is a useful process which will assist in the appropriate balancing of the competing rights and interests involved and in putting the patient’s right to health at the forefront of the discussion. ALHR believes that Australian policy, like legislation, should also be informed by the standards of international human rights so that policy represents an appropriate and proportionate response to the problems and harms being addressed.

2 Is there a need for extra regulation and should it be more clearly scoped?

- 2.1 ALHR notes the submission of the AIMA to the effect that the proposed regulations do not conform to COAG principles of best practice and are inconsistent with the World Health Organisation’s *Traditional Medicine Strategy 2014-2023*,⁸ but appear to have been presented in the Consultation as the only possible alternative to the existing rules, rather than being developed through comprehensive community consultation. In this context it is relevant to recall that an important aspect of the right to health, says the Committee on Economic, Social and Cultural Rights (CESCR), is the participation of the population in all health-related decision-making at the community, national and international levels.⁹ While the Consultation has been made public, we are concerned that it may have been too narrowly framed and effectively presents only two options; either: (1) no additional regulation, or (2) additional regulation in terms of the proposed regulations. It is to be hoped that as a result of the current process, improvements to the manner in which the three practices may be appropriately regulated will emerge.
- 2.2 We note the comments of the AIMA that it is inappropriate to impose additional regulation upon medical practitioners in relation to the three practices, given that the existing Code “Good medical practice: A code of conduct for Doctors in Australia”¹⁰ and the AMA Code of Ethics¹¹.

⁶ Op cit at 1.6.

⁷ http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf

⁸ https://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/

⁹ Committee on Economic, Social and Cultural Rights, **CESCR General Comment No. 14: *The Right to the highest attainable Standard of Health***, Adopted at the Twenty-second Session of the Committee, on 11 August 2000 (Contained in Document E/C.12/2000/4) at <https://www.refworld.org/pdfid/4538838d0.pdf>, par 11.

¹⁰ <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>,

https://ama.com.au/sites/default/files/documents/AMC_Code_of_Conduct_July_2009.pdf

¹¹ <https://ama.com.au/position-statement/code-ethics-2004-editorially-revised-2006-revised-2016>. See also the *Australian Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*.

would appear to cover all relevant issues. ALHR submits that if changes are appropriate they should be made to those documents rather than through separate regulations. An additional level of regulation would impose unnecessary additional compliance obligations on practitioners may diminish the range of treatments available to Australians.

- 2.3 Even if additional requirements or changes are appropriate we agree with other submissions that the scope of the requirements is insufficiently clear and that it is inappropriate to treat the three practices in the same way, noting their different characteristics, benefits and risk profiles.
- 2.4 The three practices are not separately defined. The joint definition of the three practices in the Consultation paper is not scientifically based and is insufficiently clear, particularly given that it could be used for disciplinary purposes (see section 6.4 below). The joint definition ‘lumps together’ practices that are all said to be not ‘conventional’ without identifying what they are other than by some discussion of examples, which discussion is not however reflected in the actual wording of the proposed regulations.
- 2.5 The joint definition (and the Consultation Paper) fail to identify whether the different treatments or practices have real or distinguishable commonalities or similar risk profiles.
- 2.6 ALHR recognises, as noted by the AMA, that, some complementary medicines “...have the potential to cause adverse reactions or interact with conventional medicine. Unproven complementary medicines and therapies can also pose a risk to patient health either directly through misuse or indirectly if a patient defers seeking medical advice.”¹²
- 2.7 ALHR notes that not all ‘non-conventional’ and emerging treatments can be categorised as lacking efficacy or as unsafe. While ALHR strongly supports evidence-based policy and regulatory initiatives aimed at ensuring patients are protected from the kinds of risks noted by the AMA, we submit that the definition of the three practices is too vague. The proposed regulations also fail to define key terms such as ‘complementary’, ‘conventional’, ‘unproven’ and ‘emerging.’ This will make it difficult for practitioners to assess whether the proposed regulations, if implemented, apply to particular treatments or not.

3. The Human Rights background

- 3.1 Australia is a state party to the *International Convention on Civil and Political Rights* (ICCPR)¹³ and to the *International Covenant on Economic, Social and Cultural Rights* (the ICESCR)¹⁴. There are now seven core international human rights law (IHRL) conventions, being: the ICCPR, the ICESCR, the:

- *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*;¹⁵
- *Convention on the Elimination of All Forms of Racial Discrimination*;¹⁶
- *Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)*;¹⁷
- *Convention on the Rights of the Child (CRC)*;¹⁸ and
- *Convention on the Rights of Persons with Disabilities*.¹⁹

¹² Op cit at 1.7.

¹³ signed by the Australian government on 18 December 1972 and ratified on 13 August 1980

¹⁴ UNGA resolution 2200A (XXI), 16 December 1966, entry into force 3 January 1976, 993 UNTS 3

¹⁵ UNGA resolution 39/46, entry into force 26 June 1987, A/39/51 (1984)

¹⁶ UNGA resolution 2106 (XX), entry into force 4 January 1969, 660 UNTS 195

¹⁷ UNGA resolution 34/180, entry into force 3 September 1981, A/34/46

¹⁸ UNGA resolution 44/25, entry into force 2 September 1990, A/44/49

¹⁹ UNGA resolution 61/106, entry into force 3 May 2008) A/RES/61/106

- 3.2 Pursuant to Article 26 of the 1969 Vienna Convention on the Law of Treaties, Australia has an obligation to the international community to implement, uphold, protect and respect all of the rights contained in the IHRL conventions, and to incorporate the effect of those conventions into its domestic law.
- 3.3 Article 12 of the ICESCR specifically provides for the right to **the highest attainable standard of health**.²⁰ “While the right to health is sometimes understood to focus only on positive guarantees for the progressive realization of the availability, accessibility, acceptability, and quality of health care for all,” say Cohen and Ezer, “it also incorporates negative guarantees for the assurance of freedom from abuse and discrimination by the state and third parties within health care service delivery.” That is, the right to health (which Australia has agreed to uphold) also includes the right to “a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.”²¹
- 3.4 The human rights specified in the core IHRL treaties normally contain further implicit rights. Thus data rights are seen as an aspect of the right to privacy. As society progresses, it is likely that perceptions will change as to the further rights implications of existing specified rights. Marriage equality, for example, was not originally perceived as a necessary result of the human rights of freedom of religion and belief, the right to equality and the right to freedom from discrimination on the basis of sex or status, but has come to be seen as the necessary consequence of the application of those rights and freedoms.
- 3.5 In this way, the human rights system can be said to be “an *evolving* or dynamic system of safeguards which does (and should) respond to our growing understanding of particular techniques of repression and of different systems of oppression.”²²
- 3.6 Many rights relating to health issues in the context of patient treatment are implicit rights. Cohen and Ezer note that:
- The provisions of these treaties have been interpreted by human rights bodies to prohibit numerous forms of abuse in health settings. For example, the right to liberty and security of the person has been held to prohibit institutionalization without due process of people with mental illness; the right to privacy has been held to prohibit unauthorized disclosure of personal health data; the rights to bodily integrity and security of the person have been held to prohibit the administration of medicine to a child against parents’ wishes; and the right to freedom from cruel, inhuman, or degrading treatment or punishment has been held to oblige governments to secure the adequate health and well-being of prisoners.*²³
- 3.7 The CESCR, in paragraph 12 of its *General Comment No. 14*, describes a number of rights and implicit rights that it sees as integral to the rights to health and to bodily integrity (as does the European Charter of Patients’ Rights, discussed below). These rights include:
- Availability (par 12(a)) of health treatment and the underlying determinants of health, without discrimination;
 - Accessibility (par 12(b)) including the right to seek, receive and impart information and ideas concerning health issues ;

²⁰ See also Article 5, ICERD, Article 24, CRC, Article 12(1) CEDAW, Article 16, *African Charter on Human and Peoples’ Rights*, articles 11 and 13, *European Social Charter*.

²¹ CESCR General Comment No. 14, par 8.

²² Morton Winston, *On the Indivisibility and Interdependence of Human Rights*, Paper presented to 20th World Congress of Philosophy conference, 11 August 1998, Boston University Website, <https://www.bu.edu/wcp/Papers/Huma/HumaWins.htm>, 4 -5, citing Johannes Morsink, ‘World War II and the Universal Declaration,’ *Human Rights Quarterly*, vol 15(2), 1993, 357.

²³ *Jonathan Cohen and Tamar Ezer, “Human rights in patient care: A theoretical and practical framework” (2013) 15 (2) Health and Human Rights Journal*, available at <https://www.hhrjournal.org/2013/12/human-rights-in-patient-care-a-theoretical-and-practical-framework/>

- Acceptability (par 12(c)): meaning that health services must be “respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, [and] sensitive to gender and life-cycle requirements”;
- Quality (par 12(d)): to the observance of quality standards, with services being scientifically and medically appropriate.

3.8 The European Charter of Patients’ Rights²⁴ drafted by the Active Citizenship Network puts the implicit right to health information as key to the health rights of patients, saying that every individual:

- “has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available”²⁵
- “has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health”²⁶
- “has the right to freely choose from among different treatment procedures and providers on the basis of adequate information”²⁷ and
- “has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.”²⁸

However it should be noted that this Charter, although influential in the European human rights context according to Cohen and Ezer, is written from the paradigm of patients as consumers, which is a different viewpoint from the broader (and in our view preferred) concept of patients as holders of human rights and as entitled to be treated with dignity.

3.9 The Committee notes²⁹ that inappropriate resource allocation can lead to “discrimination that may not be overt. For example, investments should not disproportionately favour expensive curative health services which are often accessible only to a small, privileged fraction of the population, rather than primary and preventive health care benefiting a far larger part of the population.” In addition, the Committee comments that “indigenous peoples have the right to specific measures to improve their access to health services and care,” saying that such health services “should be culturally appropriate, taking into account traditional preventive care, healing practices and medicines.”³⁰

3.10 One intriguing implicit health right that has been argued for in the context of patient care is the ‘right to the placebo effect.’ In the context of today’s norm of ‘medical pluralism’, Gemma Burford examines Article 24 of the 2007 *Declaration on the Rights of Indigenous People*, which states that indigenous people have the right to their traditional medicines and health practices. The principle underlying this article is, she notes, that people heal better when treated in a

²⁴ http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf

²⁵ Op cit, p 4.

²⁶ Op cit, p 5.

²⁷ Op cit, p 5.

²⁸ Op cit, p 7. See also ICESCR (see note 13), Art. 15 as to the right to the benefits of scientific progress.

²⁹ CESCR, op cit, par 19.

³⁰ Op cit, par 27. However Mpinga et al comment (text prior to footnote 56) that the CESCR “takes a reductionist view by framing the question of [non-conventional medicines] as a matter of interest and concern only for native people”, noting that “[i]n doing this, the Committee misses what current data show, namely that everybody (including urban populations) resorts to non-conventional and complementary medicines.”

culturally familiar way by those whom they trust.³¹ Thus if indigenous people have a right to indigenous medicine and health carers they are therefore more likely to have the benefit of the (evidence-based) placebo effect. Conversely, if they are treated in a culturally unfamiliar way they may suffer from the opposite, the nocebo effect.

- 3.11 A human-rights-based framework for patient care is increasingly being seen as a desirable alternative to consumer or contract-based ‘patient rights’ frameworks. A human rights framework considers the rights (and obligations) of both patient and provider, as well as wider social interests. As Cohen and Ezer say,

*the human rights in patient care concept refers not just to entitlements for actual patients, but also to human rights standards in the provision of care that concern health providers and the entire community. It calls for a pervasive human rights frame to govern the delivery of care to patients in all its aspects, which also highlights equality, participation, transparency, and accountability concerns.*³²

4. Applying a human rights framework³³

The balancing of indivisible and interdependent human rights

- 4.1 International human rights law has developed a process or set of principles by which conflicts can be managed, both within the realm of human rights alone and in relation to external issues.

Rights must be balanced where they conflict

- 4.2 In general terms, no human right ‘trumps’ any other right – all are equally valuable (the principle of indivisibility) and should be protected together (the principle of interdependence).
- 4.3 Some rights are expressed as absolutes, such as the right to be free from slavery, torture, cruel or inhuman or degrading punishment or treatment, or arbitrary deprivation of life, and the right to recognition as a person in law.³⁴
- 4.4 Subject to those absolutes, all rights must be **balanced** where they conflict **so as to maximise the practice of other rights to the greatest possible extent**, in ‘an atmosphere of mutual consideration’³⁵ and so as to ‘ensure that none is inappropriately sacrificed’.³⁶ This is sometimes described as a process of providing **reasonable accommodation** to other rights and other persons: ‘a fair balance needs to be struck between the rights of the individual and the rights of others.’³⁷ This is similar to the test of proportionate response to the harm in

³¹ “Citizen’s choice of preferred system of healthcare as a fundamental human right” (2010) *Journal of Ayurveda and Integrative Medicine*, Jan-Mar 1(1), 22 -25 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3149387/>

³² Op cit.

³³ See generally “What is a human rights-based approach?” François-Xavier Bagnoud (FXB) Center for Health and Human Rights at the Harvard School of Public Health, *Health and Human Rights Resource Guide* (5th ed) at <https://www.hhrguide.org/153-2/>

³⁴ See generally Attorney-General’s Department Public Sector Guidance Sheet: *Absolute rights* at <https://www.ag.gov.au/RightsAndProtections/HumanRights/Human-rights-scrutiny/PublicSectorGuidanceSheets/Pages/Absoluterights.aspx>

³⁵ Grimm, op cit, 2382.

³⁶ Alice Donald and Erica Howard, *The right to freedom of religion or belief and its intersection with other rights*, ILGA-Europe Research Paper, 2015, p i available at: <https://www.ilga-europe.org/sites/default/files/Attachments/the_right_to_freedom_of_religion_or_belief_and_its_intersection_with_other_rights__0.pdf>.

³⁷ *Ibid*, p i.

question which is generally used to assess whether or not legislation or policy is too wide in its scope.

Taking account of context and other values

- 4.5 The balancing and reasonable accommodation tests are very much dependent upon context and cannot be used in the abstract. They may also need to call upon other rights and other values (such as reasonableness or proportionality).
- 4.6 Human rights can validly be restricted if the restriction is prescribed by law and is necessary for the protection of public safety, public health or morals or for the protection of the rights and freedoms of others.

The good faith of those seeking protection

- 4.7 Human rights entail **both rights and obligations**. **Where protection is desired for particular behaviour it will be relevant to what extent that behaviour reflects respect for the rights of others**. Generally, behaviour should not be protected by Australian law, nor advocated by policy, where that behaviour itself infringes other human rights.
- 4.8 In balancing the competing claims, it is important to minimise any negative impact; to impinge as little as possible upon other rights.
- 4.9 That is, where there is a conflict between human rights and other interests it may be necessary to limit or constrain the other interests if they are to be implemented in a way that limits the free exercise of human rights.

How this framework operates in relation to patient care

- 4.10 On the one hand a human rights framework in relation to patient care can support the right to the highest attainable standard of health and associated rights such as privacy, security of person, right to life, right to bodily integrity, right to information, right to non-discrimination and equal treatment, right to freedom from inhuman or degrading treatment, and can highlight matters such as equality, participation, transparency, and accountability.
- 4.11 At the same time, because of the balancing process referred to above, a human rights framework can be more flexible than a patients' rights paradigm in regard to necessary limitations on the rights of patients and providers. As Cohen and Ezer say, the patients' rights paradigm does not automatically recognize the need to place limitations on rights in the health context, whereas a human rights framework "enables a more systemic, balanced approach that recognizes that the rights of no single patient are absolute" and must be balanced with competing rights and needs.
- 4.12 A human rights approach can also provide a framework for solving bioethical dilemmas. Human rights add to bioethics both 'a method for arriving at concrete decisions' about how to judge complex and ethically challenging clinical interactions, and a set of procedures for enforcing those decisions.³⁸
- 4.13 Key patient rights are seen, say Cohen and Ezer, as the rights to liberty and security of the person; privacy; information; bodily integrity; life; highest attainable standard of health; freedom from torture, cruel, inhuman, and degrading treatment; participation in public policy; non-discrimination and equality.

³⁸ Cohen and Ezer, op cit, text at footnote 31, quoting S. Marks, "The new partnership of health and human rights," (New York: Carnegie Council for Ethics in International Affairs, May 16, 2001). Available at http://www.carnegiecouncil.org/publications/archive/dialogue/2_06/articles/650.html.

- 4.14 Key provider rights are seen as the rights to decent work conditions;³⁹ freedom of association;⁴⁰ and due process.⁴¹
- 4.15 Given that the rights to the highest attainable standard of health and to bodily integrity also encompass the related rights mentioned in paragraph 3.4, ALHR submits that the proposed regulations would unduly inhibit those rights.
- 4.16 The CESCR has emphasised in the context of the right to health that the ICESCR's limitation clause (article 4), is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States. The CESCR concludes that a State party which seeks to impose medical restrictions has the burden of justifying those restrictions which "must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society."⁴² Further, "such limitations must be proportional, i.e. the least restrictive alternative must be adopted where several types of limitations are available."⁴³ ALHR questions whether the proposed regulations only impose minimal and proportional limitations upon the practice of 'non-conventional' medicine.

5. The roles of Provider and Patient

Provider

5.1 ALHR supports the position of the AMA that:

- "Medical practitioners should be able to explain the level of evidence for all medicines and therapies they utilise to help patients make an informed choice."⁴⁴
- "Medical practitioners should have access to education about complementary medicine in their undergraduate, vocational and further education to provide advice to patients. They should be informed of the level of scientific evidence for both benefits and adverse reactions, including potential interactions with other medicines."⁴⁵

As Cohen and Ezer note,

*... the concept of human rights in patient care recognizes health care providers as important actors, whose rights must be respected both as a matter of principle and for the benefit of the patient. The relationship between patient and provider rights is critical. Providers are unable to provide high-quality care unless their rights are respected and they can work under decent conditions with professional independence.*⁴⁶

5.2 Viewing the provider in this manner can be relevant where conflicts of interest exist between the provider (and their duty to their patients) and the state. The International Dual Loyalty Working Group, established by Physicians for Human Rights, has identified many potential areas of conflict of interest between medical professions and the state, including some known to us here in Australia such as requiring medical professionals to remain silent about the medical

³⁹ ICESCR 7, ACHPR 15, European Social Charter 2-4

⁴⁰ ICCPR 21, ACHPR 10, ECHR 5, 11

⁴¹ ICCPR 14(1), ACHPR 7, ECHR 6(1).

⁴² Op cit, par 28.

⁴³ Op cit, par 29.

⁴⁴ Op cit at 4.4.

⁴⁵ Op cit at 4.

⁴⁶ Op cit.

consequences of human rights abuses committed against individuals and groups.⁴⁷ Identifying situations of “dual loyalty”, say Cohen and Ezer, “sheds light on the causes and manifestations of human rights abuses in patient care, and it also provides a framework for preventing abuse by resolving dual loyalty conflicts in a fair and transparent manner.”⁴⁸

Negative Practical Implications

- 5.3 It is submitted that the proposed regulations, if implemented, would negatively effect practitioners (and patients) in two ways, because of the additional compliance burdens imposed, being that:
- (a) they would discourage practitioners already engaged in the three practices from continuing to access education on practices; and
 - (b) they would discourage ‘conventional’ practitioners from being educated on the three practices.

Right to due process

- 5.4 It is submitted that the vague nature and general lack of definitions in the proposed regulations mean that it will be difficult for practitioners to assess when the guidelines apply and that it is therefore quite inappropriate that the proposed regulations be useable in relation to legal or disciplinary measures against practitioners. However Section 41 of the *Health Practitioner Regulation National Law 2009* states that “an approved registration standard or a code or guideline approved by a National Board is admissible in proceedings under [the] Law or a law of a co-regulatory jurisdiction against a health practitioner registered in a profession for which the Board is established as evidence of what constitutes appropriate professional conduct or practice for the health profession”. It would therefore appear that the proposed regulations, although not based on evidence as to risk or negative outcomes, and although definitionally quite unclear, are capable of being used for disciplinary purposes.

The Patient

- 5.5 Human rights in patient care, say Cohen and Ezer, aims to move away from a biomedical model focusing only on the nature and quality of patient services towards one in which patients are active agents in their health. Full information and informed consent is key to the ‘active agent’ approach so that patients are empowered to make health care choices on the basis of complete information about the efficacy and safety of all available alternatives.
- 5.6 Patients should have access to accurate information and education about the level of evidence for complementary medicines and therapies in order to make well-informed choices. This should include the risks and opportunity costs of delaying conventional treatment.⁴⁹

Negative Practical Implications

- 5.6 As mentioned above, the negative consequences for patients of implementation of the proposed regulations in their current form is the risk of a reduction in the range of available treatments. Practitioners are likely to be discouraged from offering non-conventional

⁴⁷ See Bianca Hall, “‘A huge win for doctors’: Turnbull government backs down on gag laws for doctors on Nauru and Manus, *The Sydney Morning Herald*, 20 October 2016, available at: <https://www.smh.com.au/politics/federal/a-huge-win-for-doctors-turnbull-government-backs-down-on-gag-laws-for-doctors-on-nauru-and-manus-20161020-gs6ecs.html>, relating to amendments to the *Border Force Act*, AAP, “Australian doctors rally over threat of jail for speaking about asylum seekers”, *Guardian Online*, 11 July 2015, available at: <https://www.theguardian.com/australia-news/2015/jul/11/australian-doctors-rally-over-threat-of-jail-for-speaking-about-asylum-seeekers>.

⁴⁸ Op cit.

⁴⁹ Op cit at 5.1.

treatments of any kind for fear of falling under the additional obligations and monitoring that will result.

Regulation of medications

5.7 ALHR strongly supports the position of the AMA that:

- *“The majority of complementary medicines do not meet the same standards of safety, quality and efficacy as mainstream medicines as they are not as rigorously tested. Information about the level of testing and evidence should be easily accessible by medical practitioners, consumers and complementary medicine practitioners.*
- *In the absence of sufficient efficacy data, it is essential there be clear and true statements regarding the efficacy and standards of evidence relied on, including accurate labelling.*
- *Government agencies such as the Therapeutic Goods Administration (TGA) and educational bodies such as the National Prescribing Service should ensure information on the safety, quality, efficacy and cost effectiveness of complementary medicines is readily available to consumers and health practitioners.*
- *Consumers and health practitioners should ensure they promptly report any adverse events they suspect are caused by a complementary medicine to the TGA.*
- *The AMA supports the TGA’s public database of medicine adverse events notifications.”⁵⁰*

6. Conclusion

While ALHR submits that the proposed regulations do not strike an appropriate balance in protecting patient choice as an integral part of the right to health, ALHR strongly supports appropriate regulation of integrated medicine practitioners and their activities.

The existing Code “Good medical practice: A code of conduct for Doctors in Australia”⁵¹ and the AMA Code of Ethics⁵² would appear to cover all relevant issues. ALHR submits that if changes are appropriate they should be made to those documents rather than through separate regulations.

ALHR further submits that a human rights framework complements bioethics by providing a set of legally recognised and globally accepted norms and procedures for identifying systemic issues and balancing individual rights with appropriate limitations.

It is submitted that an information-based human rights framework is preferable to the proposed regulations because it will ensure that:

1. Patients are empowered to be active participants in receipt of the full suite of information required for the proper provision of informed consent in choosing the treatment that is most appropriate for their personal situation; and
2. Clinicians are obliged to provide treatment that is has scientific proofs and sufficient guarantees regarding its safety and efficiency.

⁵⁰ Op cit at 6.

⁵¹ <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>,
https://ama.com.au/sites/default/files/documents/AMC_Code_of_Conduct_July_2009.pdf

⁵² <https://ama.com.au/position-statement/code-ethics-2004-editorially-revised-2006-revised-2016>. See also the *Australian Code for the Responsible Conduct of Research* and the *National Statement on Ethical Conduct in Human Research*.

If you would like to discuss any aspect of this submission, please email me at: president@alhr.org.au

Yours faithfully

Kerry Weste

President

Australian Lawyers for Human Rights

Any information provided in this submission is not intended to constitute legal advice, to be a comprehensive review of all developments in the law and practice, or to cover all aspects of the matters referred to. Readers should obtain their own legal advice before applying any information provided in this document to specific issues or situations.