McCABE CENTRE FOR LAW & CANCER

Making the law work better for people affected by cancer

2014 Report

Cancer Council Victoria

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McCABE CENTRE FOR LAW & CANCER

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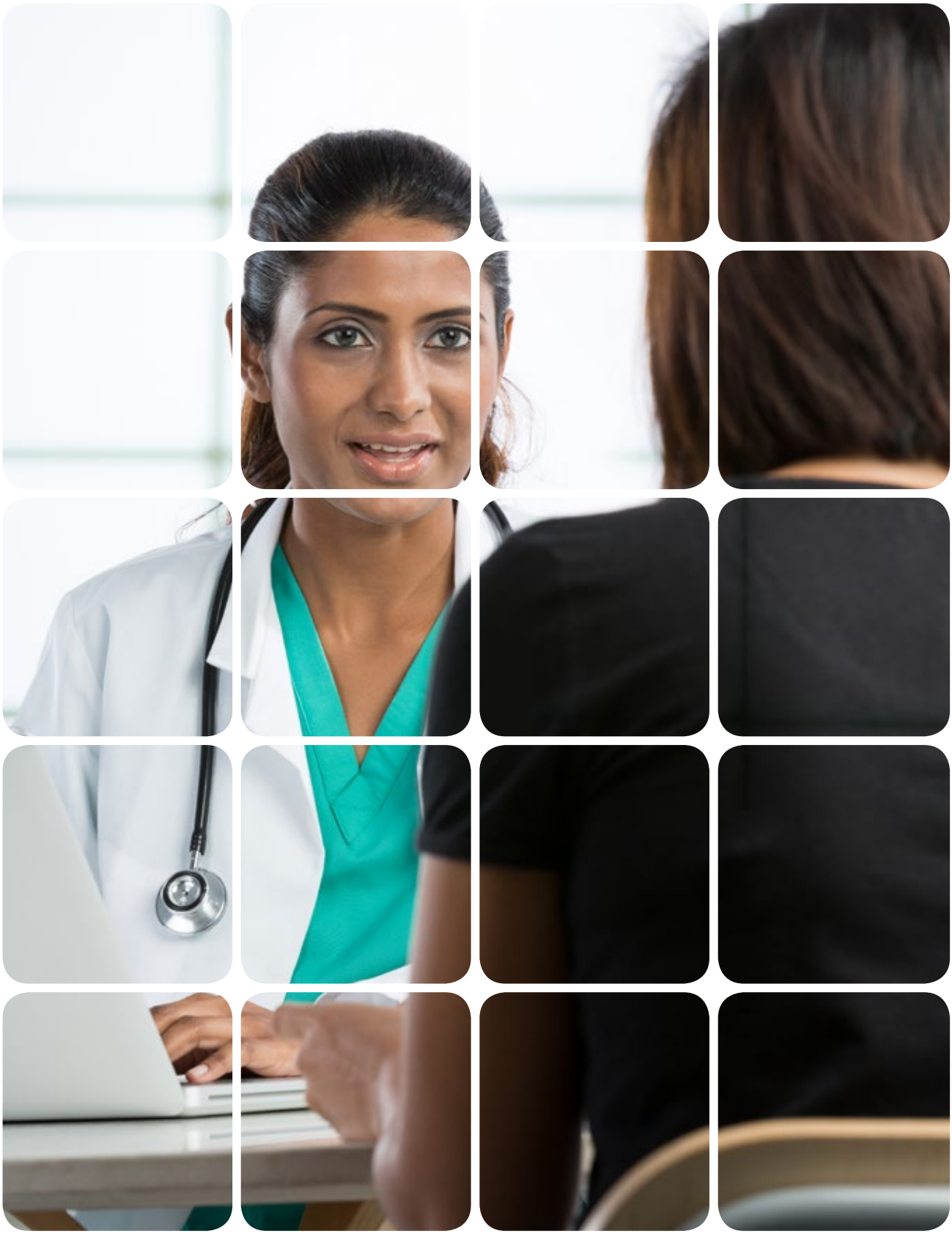


GLOSSARY

ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law
AHMAC	Australian Health Ministers' Advisory Council
AMA	Australian Medical Association
ARTG	Australian Register of Therapeutic Goods
BCNA	Breast Cancer Network Australia
CAM	Complementary and Alternative Medicines
CAV	Consumer Affairs Victoria
CBRC	Centre for Behavioural Research in Cancer
CCV	Cancer Council Victoria
CISS	Cancer Information and Support Service
COSA	Clinical Oncology Society of Australia
GPs	General Practitioners
HCCC	Health Care Complaints Commission (NSW)
IFC	Informed Financial Consent
MBS	Medicare Benefits Schedule
NHMRC	National Health and Medical Research Council
NRAS	National Registration and Accreditation Scheme
OHSC	Victorian Office of the Health Services Commissioner
PBS	Pharmaceutical Benefits Scheme
PCFA	Prostate Cancer Foundation of Australia
SCOH	Standing Council on Health
TGA	Therapeutic Goods Administration
UICC	Union for International Cancer Control
VCAT	Victorian Civil and Administrative Tribunal
VPTAS	Victorian Patient Transport Assistance Scheme

Making the law work better for people affected by cancer

EXECUTIVE SUMMARY

The McCabe Centre for Law and Cancer is examining the laws and policies that impact on Victorians diagnosed with cancer, their families and health professionals. The focus of the project so far has been laws and policies relating to:

1. Access to cancer treatment, especially transport and accommodation support for rural and regional Victorians;
2. Employment-related issues, particularly discrimination in the workplace;
3. Discrimination in obtaining insurance, including in relation to the use of genetic testing; and
4. End of life decision-making, including substitute decision-making and advance care directives.

In 2014, the project focus expanded to include analysis of:

1. Informed consent to cancer treatment, including informed financial consent (IFC); and
2. The regulation of unregistered complementary and alternative medicine (CAM) practitioners.

Our recommendations in relation to these areas are set out below.

Informed consent and cancer care

Informed consent, also known as informed decision-making, is grounded in the principle of individual and personal autonomy, and is a fundamental component of a patient centred-care approach. Informed consent laws and guidelines are intended to articulate the rights of patients, and the obligations of health professionals, to make or facilitate the making of, informed decisions about medical treatment.

Valid informed consent depends on the presence of three key elements: the provision of adequate information; the capacity or ability of the decision-maker to understand the information; and the voluntary nature of the decision, that is, that the decision is free from coercion. These components are intersecting and interdependent, and rely heavily on the ability of a health practitioner to communicate the relevant information, and the decision-maker to understand the relevant information.

The notion of IFC raises similar complexities in relation to the obligation of a health professional to communicate relevant information and the ability of a decision-maker to understand the relevant information.

Our report examined medical practitioners' legal and professional obligations regarding informed consent, including IFC; the barriers that may inhibit or prevent informed consent from being obtained; and Victorian cancer patients' experiences of receiving information about diagnosis and treatment from their medical doctors.

The law around informed consent is well established, and the legal and professional requirements of doctors regarding informed consent appear to be adequately set out by National Health and Medical Research Council (NHMRC) and Australian Medical Association (AMA) guidelines, and flexible enough to provide effective guidance in a cancer care setting.

However, the application of the law in practice, and adherence to professional guidelines may not be consistent. Feedback from our survey and focus groups indicated that while most Victorian cancer patients felt that they were able to make an informed decision about their treatment, many patients felt that they did not receive enough relevant information with regard to specific areas required by law and the professional guidelines—including information on potential side-effects or complications—and some did not feel that overall they were able to make an informed decision about treatment.

Barriers that can inhibit or prevent informed consent from being obtained included patients feeling overwhelmed and in shock from their cancer diagnosis, a perceived lack of time for consultations, and the speed at which some patients progress from receiving a diagnosis to treatment.

In relation to the costs of medical treatment and IFC, while the principles of IFC, as reflected in professional guidelines, appear to encompass the primary responsibility of medical practitioners to communicate the potential costs of medical treatment, feedback from survey participants and focus group attendees echoed findings in other reports[1], which indicate that many cancer patients experience are concerned about the costs of cancer treatment, including out-of-pocket medical costs.

Based on our analysis of informed consent laws and guidelines, and taking into account feedback from patients, obtained through our survey and focus groups, we make the following recommendations and suggest some next steps.

Recommendations

1. Greater consistency in informed consent processes is required within the medical profession.
2. Further education or training to improve doctors' knowledge of the purpose of informed consent processes, their professional obligations and best practice in the provision of information to patients.
3. Better mechanisms to ensure patients are fully informed about treatments costs.
4. Supporting doctors to discuss obvious non-medical costs with their patients, especially those that may be relevant to the patient's treatment decision.

Next steps

1. The McCabe Centre for Law and Cancer will work with CCV's Cancer Information and Support Services (CISS) and Clinical Network to provide information and guidance to medical practitioners and consumers to better understand informed consent and IFC principles, processes and requirements.
2. The McCabe Centre, CCV's CISS and Clinical Network to review and update CCV's patient rights information.
3. Regarding costs and IFC, a next step in this project may be to review the approach of the doctors, hospitals and medical centres that do have effective IFC mechanisms in place to identify and articulate best practice approaches.
4. CCV's CISS and Pro Bono Legal Service will continue to develop and provide information and to health professionals and patients about common cancer-related non-medical costs and services that can offer support.

Barriers that can inhibit or prevent informed consent from being obtained included patients feeling overwhelmed and in shock from their cancer diagnosis, a perceived lack of time for consultations, and the speed at which some patients progress from receiving a diagnosis to treatment.

The regulation of complementary and alternative medicine practitioners and Victorian cancer care

The use of complementary and alternative therapies among cancer patients in Australia is common. However, while the use of some complementary therapies, for example yoga and massage, is safe and may have benefits, there have been several high profile examples of unscrupulous CAM providers taking advantage of vulnerable individuals, often at great expense and at times, high risk to the patient. Not all CAM practitioners are required to be registered and these cases have highlighted a gap in the regulatory framework for CAM practitioners. Whereas registered health practitioners are governed by professional Boards with the power to set standards and discipline member practitioners, there is limited oversight of unregistered practitioners. Given the high use of CAM among cancer patients, including therapies provided by unregistered practitioners, having appropriate regulatory mechanisms to protect the public from unregistered CAM practitioners who fail to meet a reasonably expected standard of competency, ethics and efficacy, is important.

New South Wales, South Australia and Queensland have all recently moved to introduce negative licensing schemes in relation to unregistered health practitioners. Negative licensing schemes do not restrict entry to practice, like other business or occupational licensing schemes, but allow action to be taken against practitioners who fail to comply with specified standards of conduct or practice.

In 2013, the Australian Health Ministers' Advisory Council (AHMAC) recommended a national negative licensing scheme, in the form of a national statutory Code of Conduct, and strengthened health complaints mechanisms. The Council of Australian Governments' Standing Council on Health agreed to these recommendations, and directed AHMAC to develop a draft National Code of Conduct. This Code will be considered by state and territory Health Ministers in early 2015.

Our report examined: the regulatory framework that applies to unregistered health practitioners in Victoria, including practitioners of CAM; the use of CAM by people affected by cancer; the efficacy of existing regulatory mechanisms in Victoria; and options for reform, including recommendations of AHMAC. Based on this analysis, we make the following recommendations and suggest some next steps.

Recommendations

1. We support the proposed negative licensing model, as proposed in the draft National Code of Conduct, as it appears to provide a cost-effective means of protecting the public from incompetent, unethical or impaired practitioners. We believe that a model that incorporates a national Code of Conduct, and comparable penalty provisions, would be preferable for consistency. However, if agreement among the states and territories cannot be reached, Victoria should consider implementing a scheme with a Code of Conduct based on the draft Code of Conduct developed by AHMAC.

2. The AHMAC draft code has gone through extensive consultation and we broadly support it in its current form. However, based on consultations with our expert working group, we believe that consideration should be given to amending the code to directly address the situation in which a CAM practitioner claims to be able to prolong the life of a person with cancer (or other serious illnesses), without appropriate evidence.

3. We also recommend that the draft National Code be amended to be explicit that health practitioners must obtain their client's 'informed consent', not just 'consent'. This would help remind unregistered practitioners that they are subject to common law informed consent laws. To be consistent with informed consent standards that apply to the medical profession, it would also be helpful for the code to more closely reflect the Medical Board of Australia and NHMRC Guidelines (outlined in the informed consent section of this report)[2].

4. If Victoria adopts its own Code of Conduct that differs materially from that developed through the AHMAC process, it is important that the government engage with stakeholders on its content.

5. It is essential that the Office of the Health Services Commissioner is provided with sufficient resources to adequately administer and enforce any future Code of Conduct that may be adopted.

6. It is essential that any future negative licensing scheme is closely monitored to ensure that it meets its intended purpose and does not have any unintended negative consequences.

Next steps

1. Working with the Victorian Government to develop and implement comprehensive reforms, including a negative licensing system

2. Together with CCV's Cancer Information and Support Services, and Clinical Network, review CCV's CAM education and information materials for patients to ensure that they are clear about the extent of regulation of many CAM practitioners, and avenues for complaints if patients are unhappy with the conduct of CAM practitioners, or the treatment they have received.

THE PROJECT

Cancer is a leading cause of disease in Victoria with 81 new diagnoses and 30 deaths from cancer every day.[3] In 2013, nearly 30 000 Victorians were diagnosed with cancer and over 11 000 died,[4] although survival rates are increasing.[5] One in three Victorians will develop a cancer by the age of 75.[6]

In 2012 the McCabe Centre for Law and Cancer commenced a project—*Making the Law Work Better for People Affected by Cancer*—supported by the Legal Services Board of Victoria Major Grants program. The purpose of the project is to analyse the laws and policies that impact Victorians affected by cancer, encourage discussion about the impacts of these laws, and formulate recommendations for law and policy reform where appropriate (see http://www.mccabecentre.org/focus-areas/treatment-and-support/making-law-work-cancer).

While the focus of the project is cancer care in a Victorian context, the project has national relevance, because local experiences of cancer are impacted by national laws, policies and professional guidelines, as well as broader relevance for people with other chronic or life-limiting diseases, because many of the issues we address are common across other diseases. However we also recognise that some of these issues may be more acute for people affected by cancer, for example, the need for specialist treatment and limited locations of specialist treatment centres requiring people to travel for cancer care, or the complexity of some cancer treatments impacting on issues such as informed consent.

In 2014, the project continued work on issues from 2012/13 and examined two further topics:

1. Informed consent to cancer treatment, including the issue of costs (IFC); and
2. The regulation of unregistered CAM practitioners.

These issues were selected based on consultations with the project's steering committee in phase 1 of the project (2012-13), as well as other stakeholders.

In preparing our report on the new focus areas, we undertook several modes of research, including:

- A review of relevant health and medico-legal literature;
- Consultations with our expert working group, including two roundtable discussions at CCV;
- Developing two consultation papers; and
- Conducting an online survey and focus groups with Victorian cancer patients regarding their experiences of providing informed consent to treatment.

Roundtable discussions were held at CCV on 20 October and 25 November 2014. These were attended by members of our expert working group (comprised of medical professionals and health and legal experts) and other stakeholders. The roundtables allowed discussion of the issues identified in the consultation papers in greater depth and feedback on the design of the informed consent survey and focus groups.

We received positive feedback at these events and the input of participants assisted us to improve the quality of the research for this report.

During 2014 we also continued our work on the four issues examined in phase 1 of the project (2012-13), namely:

1. Access to cancer treatment, especially transport and accommodation support for rural and regional Victorians;
2. Employment-related issues, especially discrimination;
3. Discrimination in obtaining insurance, including in relation to the use of genetic testing; and
4. End of life decision-making, including substitute decision-making and advance care directives.[7]

Our work on these areas in 2014 is briefly outlined below. The remainder of the report is focused on the issues of informed consent and the regulation of unregistered CAM practitioners.

VPTAS Alliance Members

Support for rural and regional Victorians travelling for treatment

In 2014, the McCabe Centre, together with CCV's Strategy and Support Division, the Clinical Network,[8] and a newly formed alliance of agencies with a shared concern about patient accommodation and support, continued to advocate for improvements to the Victorian Patient Transport Assistance Scheme (VPTAS).

Throughout the year, we regularly sought the support of our 30 alliance member agencies for various advocacy efforts, and kept in touch through monthly updates.

A small steering committee was formed in 2014 to drive work on VPTAS related advocacy. The steering committee consisted of representatives from the McCabe Centre for Law and Cancer (Deborah Lawson, Legal Policy Advisor, and Sondra Davoren, Senior Legal Policy Advisor), CCV's Strategy and Support Division (Nicola Quin, Director) and Kidney Health Australia (Luke Toy, General Manager, Public Affairs, and Sarah Smith, Government Relations Advisor).

The steering committee coordinated pre-State budget advocacy work, including a meeting with Department of Health representatives.

In the State Budget in May, an additional $13.8 million in funding for the VPTAS was announced. CCV and Kidney Health Australia led the media release on behalf of the alliance, responding to this announcement. Following the budget announcement, the steering committee continued to represent the VPTAS alliance in ongoing advocacy to the State Government, to ensure the additional funding was realised.

In November 2014, we were notified that VPTAS subsidies had been increased. Accommodation support payments increased from $35 plus GST to $41 plus GST per night, and the reimbursement for petrol increased from 17 cents to 20 cents per km.

While these increases are a move in the right direction, they still fall well short of the increases and other improvements called for by the alliance. They remain inadequate for Victorians who have to travel for specialist treatment, especially in comparison to subsidies in other states and territories.

In 2015, we will continue to press for more improvements to the VPTAS, including by matching subsidy rates in other states and territories. In addition, we will be reiterating the agreed objectives of the VPTAS alliance, which are to:

- Increase the VPTAS subsidies to
  - 30 cents per km for petrol; and
  - $75 (+ GST) per night for accommodation
- Introduce indexing of subsidies against the Consumer Price Index; and
- Improve administration, to allow for online processing and prepayment for accommodation costs.

Advance care planning education for rural and regional GPs

In 2014 the McCabe Centre partnered with the Gippsland Region Palliative Care Consortium and the Office of the Public Advocate (Victoria) to deliver training to rural and regional General Practitioners (GPs) to assist GPs in formalising advance care planning and end-of-life care discussions in their standard practice. GPs can play a key role in advance care discussions and planning, particularly for people from rural and regional areas, who often have less access to various support services.

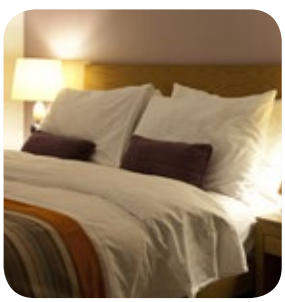
In Victoria, there are a range of advance care planning mechanisms, including completion of an advance care directive (which documents the decisions about medical care a patient would or would not choose in the future), statutory appointments of a substitute decision maker (appointed under powers of attorney, guardianship and other laws), and the making of a refusal of treatment certificate[9]. The complexity of the laws relating to these processes is a barrier for GPs wanting to discuss advance care planning with their patients.

The education sessions involved training delivered by legal experts about the laws relating to advance care planning, as well as clinical insights on conversations about death and dying. This helped to familiarise GPs with the legal and practical components of advance care planning, such as the legal process for appointing a substitute decision-maker, and how to raise this with patients.

The sessions were delivered in two parts and around 12 GPs and allied health professionals attended each seminar. The first seminar was held in May 2014 and focussed on communication skills. The second seminar addressed advance care planning laws and was held in August 2014.

The response from GPs was positive, with the majority of participants reporting that the training increased their understanding of how to raise the topic of advance care planning with patients and increased their knowledge of the laws relating to advance care planning.

In August we presented on the education sessions at the International Conference on End of Life: Law, Ethics, Policy and Practice in Brisbane. The McCabe Centre is planning to expand the training to other regions, with a focus on delivering in person and web-based education sessions.



Enhancing community knowledge and engagement with law at the end of life

In 2014 the McCabe Centre and CCV's Strategy and Support Division partnered with Queensland University of Technology's (QUT) Centre for Health Law Research in a successful Australian Research Council Linkage Grant application. The project, 'Enhancing Community Knowledge and Engagement with Law at the End of Life' is being led by QUT Law Professors Ben White and Lindy Willmott, with Cancer Council Queensland and Cancer Council NSW also partnering.

The project is exploring how and if members of the community understand and act upon their legal right to participate in decisions about medical treatment for themselves, or for their loved ones, at the end of life. The research, focused on the jurisdictions of Victoria, Queensland and New South Wales, will address three key issues:

1. Whether people affected by cancer and their substitute decision-makers know their legal rights and duties in relation to decisions about life-sustaining treatment;
2. The current practice of cancer patients when making decisions about life-sustaining treatment (including where conflict with health professionals and health systems arise); and
3. How patients can be better supported to make decisions that accord with their legal rights and duties.

The research aims to enhance patient and family decision-making through a better understanding of legal rights, powers and duties and to improve the experiences of patients and families at the end of life. The research will also inform recommendations to government to improve law, policy and practice in this area.

New and proposed legislation for powers of attorney and guardianship in Victoria

In 2014, a new *Powers of Attorney Act 2014* (Vic) (POA Act) was passed, and the Guardianship and Administration Bill 2014 was introduced, addressing, amongst other things, some of the complexities regarding substitute decision-making at end of life. The POA Act comes into force on 1 September 2015.

The Guardianship and Administration Bill was not passed before the 2014 state election and will need to be considered by the new Parliament.

In our 2013 report, we noted the need for law reform in relation to specific areas of end of life law, echoing the recommendations in the Victoria Law Reform Commission's *Guardianship: Final Report* (Guardianship Report) with regard to documenting wishes about the future, which stated that there should be a broader statutory right to make an advance care directive, encompassing future as well as current conditions, and the ability to provide consent and refusal to medical treatments in advance. In addition, our report noted the need for greater clarity in the powers of substitute decisions makers.

The new POA Act and Guardianship and Administration Bill do not go so far as to introduce legislated advance care directives; however both seek to modernise the agency guardianship concepts underpinning powers of attorney and guardianship arrangements, and to more clearly define the powers and obligations of attorneys and guardians, and the concept of decision-making capacity, which is central to the POA Act and Guardianship and Administration Bill. Finally, the POA Act and Bill both include new supportive agency powers, which allow for the appointment of an agent (guardian or attorney) to support a person who has not lost decision making capacity.

Powers of Attorney Act 2014

The POA Act implements a number of the recommendations of the Victorian Parliament Law Reform Committee in their *Inquiry Into Powers of Attorney* ("the POA Inquiry"). Relevant to the focus of this project, some of the key reforms are:

- Clarification of the duties of an Attorney acting under a power;
- Introduction of a new power of 'supportive attorney'; and
- A legislated presumption of capacity, and definition of 'decision making capacity', for the purposes of the Act.

Duties of an Attorney

Section 21 of the POA Act states that Attorneys are to act 'in a way that is as least restrictive of the principal's freedom of decision and action as is possible in the circumstances' and 'so that the principal is provided with appropriate support to allow him or her to exercise his or her legal capacity to the maximum extent possible'[10] and sets out principles to guide an Attorney making a decision about a matter on behalf of a person who does not have decision making capacity. These are that an Attorney must:

a) Give all practical and appropriate effect to the principal's wishes; and

b) Take any steps that are reasonably available to encourage the principal to participate in decision making, even though the principal does not have decision making capacity; and

c) Act in a way that promotes the personal and social wellbeing of the principal, including by—

(i) Recognising the inherent dignity of the principal; and

(ii) Having regard to the principal's existing supportive relationships, religion, values and cultural and linguistic environment; and respecting the confidential information relating to the principal.

Supportive Attorney

The POA Act introduces a new power of attorney that allows an adult (the principal) to appoint a person to support them in making decisions. This new power of appointment reflects a recommendation in the Guardianship Report that called for a mechanism to assist people who have not lost decision-making capacity, to appoint someone to assist in making a supported decision.[11] The Guardianship Report made it clear that a supporter is not a substitute decision-maker; rather, the role of the supportive attorney is to: access, or assist the principal in accessing, information to enable the principal to reach a supported decision; discuss the relevant information with the principal in a way that the principal can understand and that will assist the person to reach a decision, and; to communicate, or assist the principal to communicate the decision to other people, and advocate for the implementation of the principal's decision where necessary.[12]

Presumption and definition of decision-making capacity

Section 4 of the POA Act contains a legislative presumption of capacity and further sets out guiding principles for the assessment of capacity:

(1) *A person has capacity to make a decision as to a matter (decision making capacity) if the person is able to—*

(a) *Understand the information relevant to the decision and the effect of the decision; and*

(b) *Retain that information to the extent necessary to make the decision; and*

(c) *Use or weigh that information as part of the process of making the decision; and*

(d) *Communicate the decision and the person's views and needs as to the decision in some way, including by speech, gestures or other means.*

(2) *For the purpose of subsection (1), a person is presumed to have decision making capacity unless there is evidence to the contrary.*

(3) *For the purpose of subsection (1)(a), a person is taken to understand information relevant to a decision if the person understands an explanation of the information given to the person in a way that is appropriate to the person's circumstances, whether by using modified language, visual aids or any other means.*

(4) *In determining whether or not a person has decision making capacity regard should be had to the following—*

(a) *A person may have decision making capacity for some matters and not others;*

(b) *If a person does not have decision making capacity for a matter, it may be temporary and not permanent;*

(c) *It should not be assumed that a person does not have decision making capacity for a matter on the basis of the person's appearance;*

(d) *It should not be assumed that a person does not have decision making capacity for a matter merely because the person makes a decision that is, in the opinion of others, unwise;*

(e) *A person has decision making capacity for a matter if it is possible for the person to make a decision in the matter with practicable and appropriate support.*

(5) *Despite subsection (4)(d), the fact that a person has made or proposes to make a decision that has a high risk of being seriously injurious to the person's health or wellbeing may, in conjunction with other factors, be evidence that the person is unable to understand, use or weigh information relevant to the decision or the effect of the decision.*

Guardianship & Administration Bill 2014

The Guardianship and Administration Bill, introduced in August 2014 will, if passed, extend the reforms of the POA Act, and implement a number of the recommendations made in the Guardianship Report.

Like the POA Act, a focus of the bill is greater clarity in guardianship principles, and flexibility in guardianship and administration arrangements. The bill would amend and expand the types of guardianship orders that the Victorian Civil and Administrative Tribunal (VCAT) can make, allowing the Tribunal the flexibility to make orders that more closely recognise the needs of people with impaired decision making capacity, and their families.[13] For example, clause 50 states that VCAT can appoint a single guardian for personal and financial matters, rather than a separate guardian for personal matters, and an administrator for financial matters, as occurs now.[14] This removes the need to distinguish whether a matter is a personal care matter, or financial, lessening the risk of conflict between different decision makers[15] or uncertainty about who has decision-making power in relation to different matters.

Like the new supportive power of attorney in the POA Act, the Bill introduces a 'supportive guardian' appointment that is intended to support a person who still has capacity to make decisions. A supportive guardian will be able to assist a person in the same way as a supportive attorney under the POA Act, that is, to help the principal gather and consider information, and to communicate and implement their decisions.

Clause 4 of the Bill replicates the definition of decision-making capacity and the codified presumption of capacity in the POA Act.[16]

INFORMED CONSENT AND VICTORIAN CANCER CARE

Issue overview

The importance of informed consent

In broad terms, the term 'informed consent' refers to a 'person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved'.[17]

The aim of informed consent—also referred to as 'informed decision-making'—is to enable patients to make decisions about their treatment based on an adequate understanding of their illness and available treatment options. Grounded in the ethical principles of individual autonomy and the inviolability of the body,[18] informed consent laws and medical guidelines aim to empower patients to make informed decisions about what happens to their body.

The components of informed consent are the provision of adequate information, competency and understanding on the part of the decision-maker, and that the decision be made voluntarily (free from coercion).[19] Informed consent is therefore dependent on intersecting factors, including the ability of the health practitioner to effectively communicate the relevant information, and the capacity of the decision-maker (usually the patient, but in limited certain circumstances a substitute decision-maker) to understand the information.

IFC is an important element of informed consent. It simply means that patients should be fully informed about medical costs prior to commencing a procedure or treatment, or a treatment path that may involve ongoing costs, as well as throughout any follow-up treatment.[20]

This allows patients to factor in any out-of-pocket costs (those not covered by Medicare or private health insurance) when deciding which tests or treatments to undertake.

The growing complexity of cancer care, and the rise of new, targeted and often expensive therapies, means that informed consent, including IFC, is a critical issue for cancer patients. The failure to obtain informed consent can result in negative medical or financial outcomes for cancer patients, who may have chosen a different treatment path if fully aware of the benefits and risks of available treatment options and associated out-of-pocket costs. Failure to obtain informed consent can also have severe legal and professional ramifications for medical practitioners.

Issues with informed consent in medical care

Studies have shown that some health care consumers receive inadequate information when receiving medical care in Victoria. Gogos et al, for example, reported that about 11 per cent of complaints against doctors conciliated by the Victorian Office of the Health Services Commissioner (OHSC) between 2002 and 2008 alleged deficiencies in the provision of information.[21] The majority of complaints were against surgeons—often for elective cosmetic surgery and due to a failure to properly disclose or explain the risk of complications.[22]

Unpublished research by CCV confirms that informed consent is a concern in Victorian cancer care.[23] The PROSPECT survey reported, for example, that:

- About 17 per cent of 1183 Victorian cancer patients were not given information about the advantages and disadvantages of different treatment options; and
- About 21 per cent were not told about the possible long-term side effects of their treatment.[24]

Other studies, both Australian and international, have similarly suggested that many people with cancer consider that they are not given enough information upon which to make informed decisions.[25] Patients frequently display misunderstandings about their illness, prognosis and treatment; for example, in one study a third of patients with metastatic cancer believed that their cancer was localised, and a third of patients receiving palliative treatment believed that their treatment was intended to be curative.[26]

With regard to costs, a recent Senate inquiry — *Out-of-Pocket Costs in Australian Healthcare* — reported that practices for obtaining IFC in Australian health care are often inadequate and recommended that better mechanisms are required 'to ensure patients are fully informed about treatment costs, before initial treatment as well as throughout any follow-up treatment'.[27]

CCV's PROSPECT survey found that about 67 per cent of 406 persons experienced out-of-pocket medical expenses. These costs were unexpected in 38 per cent of cases.[28] Unexpected costs mainly related to pathology tests, surgery or medications.[29]

It is known that out-of-pocket costs for cancer patients can easily reach tens of thousands of dollars,[30] and that it is common for cancer patients to experience financial difficulties, including as a result of out-of-pocket costs.[31]

Need for further research

Our review of the literature has found evidence that informed consent and IFC are both areas of concern in Australian health care. However, more information is needed regarding the extent and nature of the problem in Victorian cancer care (as well as Australian cancer care generally). Gogos' study, for example, did not indicate whether any of the complainants were cancer patients. Our own research indicates that formal complaints by cancer patients regarding informed consent or IFC appear to be uncommon. However, complaints data may not be a reliable indicator of the adequacy of informed consent processes for this group. This is because lodging a complaint about deficiencies in informed consent processes requires cancer patients to know their rights, know how and where to make a complaint and have the time, resources and motivation to do so,[32] which may be a low priority given the need to focus on their treatment and recovery, or preparing for the end of life, and deal with associated personal and financial costs.

Aims of the research

In light of the above, our informed consent project has four broad purposes:

1. To examine medical practitioners' legal and professional obligations regarding informed consent, including IFC;
2. To obtain patient feedback regarding how well legally and medically relevant information is being provided to Victorian cancer patients, and whether individuals feel able to make informed decisions about their treatment;
3. To obtain patient feedback regarding the barriers that may prevent individuals from sufficiently understanding the information they are presented with; and
4. To utilise this feedback to consider if, and how, informed consent and IFC laws, professional guidelines and practices can be improved.

While obtaining informed consent to treatment is required of all health care practitioners (including, for example, physiotherapists, osteopaths and nurses), our report is limited to examining the issue in relation to medical practitioners[33] —the major provider of treatment for cancer patients. Future research may explore the issue in relation to a broader range of health practitioners.

Medical practitioners' legal requirements and professional guidelines: a snapshot

Basic legal requirements

The legal requirements for informed consent in Australia are largely established in the principles underpinning the common law tort of medical negligence.[34] The law of negligence imposes a general duty on medical practitioners to 'exercise reasonable care and skill in the provision of professional advice and treatment' to patients.[35] This duty extends to providing sufficient information to enable patients to make an informed decision about their treatment.[36] Where this does not occur, and the doctor's negligence results in harm to the patient, compensation may be obtainable through legal action.

The leading case regarding medical practitioners' duty to inform, *Rogers v Whitaker,* established that a patient must be warned about 'material' risks—that is, a risk that is significant to his or her decision-making process.[37] A risk is 'material' if, in the circumstances of the case:

- A *'reasonable person* in the patient's position, if warned of the risk, would be likely to attach significance to it'; or
- The 'medical practitioner is or should reasonably be aware that the *particular patient,* if warned of the risk, would be likely to attach significance to it'.[38]

While *Rogers* focused on the duty to warn about material 'risks', the broader implication of the case is that a doctor has a duty to provide any information which, in the circumstances of the case, could be significant to the decision of the patient.[39] It is also important that doctors take reasonable care to ensure that their patient actually understands the information provided.[40]

Determining exactly what information a patient ought to have been told is ultimately a matter for the courts, although accepted medical practice is a significant consideration.[41]

Doctors and hospitals often use consent forms for major procedures as proof of informed consent being obtained, however, the courts do not regard such evidence as conclusive.[42] Consent forms may be legally ineffective (as a defence to wrongful non-disclosure), for example, where a patient did not have an opportunity to ask questions,[43] or because only common risks were outlined and not those that were of particular significance to the patient.[44] Similarly, while the provision of written documents such as brochures can be a useful means of providing additional or more detailed information to patients, this does not replace the need for doctors to properly discuss relevant information with their patients.[45]

The legal requirements for IFC are less clear, there being limited case law and less commentary on the matter.[46] However, the duty to inform in tort may extend to the provision of reasonable information about costs prior to treatment.[47] Additionally, private hospitals and day procedure centres In Victoria are required by law to ensure that patients are given information about fees to be charged by the hospital or centre and any likely out of pocket expenses.[48]

General principles of contract law (for example, in relation to capacity to enter into a contract, or unconscionable conduct), may apply in these circumstances, as may some consumer protection laws.

Professional codes and guidelines

Medical practitioners have professional obligations in relation to informed consent under the Medical Board of Australia's national Code of Conduct (MBA Code).[49] A breach of the MBA Code is serious for doctors, potentially resulting in a finding of unprofessional conduct[50] or professional misconduct,[51] and in the most significant cases, deregistration as a medical practitioner[52] (see for example, the *Traill* case, Box A).

Box A:
Example of disciplinary proceedings for failure to obtain informed consent

Traill v Medical Practitioners Board (Occupational and Business Regulation)[53]

Dr Traill administered unproven or experimental treatments to several cancer patients such as whole body hyperthermia treatment and 434 mghz microwave therapy treatment. One of the grounds of complaint was that through his actions, Dr Traill failed to provide adequate information to obtain informed consent. This was because patients were not advised that the treatments were not standard medical practice and had no proven benefits in the treatment of cancer.

The Tribunal agreed that informed consent had not been obtained. On the basis of this, and several other breaches of professional standards, Dr Traill was held to have engaged in unprofessional conduct. Dr Traill's registration was cancelled and he was prohibited from applying for re-registration for 3 years.

The MBA Code provides that 'good medical practice' involves obtaining informed consent prior to undertaking an examination, investigation or providing treatment.[54] For detailed guidance on informed consent requirements, the MBA Code refers doctors to two NHMRC guidelines, namely:

1. The *General Guidelines for Medical Practitioners on Providing Information to Patients* (NHMRC General Guidelines);[55] and
2. *Communicating with Patients: Advice for Medical Practitioners.*[56]

The NHMRC General Guidelines are intended to reflect a medical practitioner's duties at common law.[57] They also establish the standard of reasonable care expected by the profession. As such they provide strong legal and professional guidance as to the type of information that should be provided to patients, and how best to convey that information.

Regarding IFC, the MBA Code indicates that a doctor should 'ensure that their patients are informed about their fees and charges' and when referring a patient for investigation or treatment, advise the patient that 'there may be additional costs, which patients may wish to clarify before proceeding.'[58] The NHMRC General Guidelines also indicate that medical practitioners should discuss costs with their patients, including out-of-pocket costs (see Box B).

The MBA Code and the two NHMRC guidelines are complemented by various other professional guidelines.[59] For example, further guidance on IFC is provided by the AMA *Informed Financial Consent Guidelines.*[60]

In developing questions for our online survey and focus groups, we relied on the legal and professional obligations as set out in the NHMRC General Guidelines.[61]

Box B:
Providing information – Medical practitioners' major professional obligations

NHMRC General Guidelines

Matters that medical practitioners should normally discuss with patients

- The possible or likely nature of the illness or disease;
- The proposed approach to investigation, diagnosis and treatment, including:
  - What the proposed approach entails;
  - The expected benefits;
  - Common side effects and material risks of any intervention;
  - Whether the intervention is conventional or experimental;
  - Who will undertake the intervention;
- Other options for investigation, diagnosis and treatment;
- The degree of uncertainty of any diagnosis arrived at;
- The degree of uncertainty about the therapeutic outcome;
- The likely consequences of not choosing the proposed diagnostic procedure or treatment, or of not having any procedure or treatment at all;
- Any significant long term physical, emotional, mental, social, sexual, or other outcome which may be associated with a proposed intervention;
- The time involved; and
- The costs involved, including out of pocket costs.

(Note: the General Guidelines state that the above guidelines may be more elaborate than necessary for minor interventions or self-evident matters).

Informing patients of 'risks'

Patients should be informed about the risks of any intervention, especially those likely to influence the patient's decisions. 'Known risks should be disclosed when an adverse outcome is common even though the detriment is slight, or when an adverse outcome is severe even though its occurrence is rare'.[62]

A medical practitioner's judgement about how to convey risks can be influenced by matters such as:

- The *seriousness of the patient's condition*—for example, the manner of giving information may need to be modified if the patient is too ill or injured to understand a detailed explanation;
- The *nature of the intervention*—for example, a complex intervention requires more information, as does an intervention that is purely elective;
- The *likelihood of harm and the degree of possible harm*—the greater the risk of harm and the more serious it is likely to be, the more information that is required;
- The *questions the patient asks*—patients should be encouraged to ask questions (these help the doctor to know what information is important to the patient). Questions should be answered as fully as possible;
- The patient's temperament, attitude and level of understanding; and
- Current accepted medical practice.

Presenting information

A medical practitioner should:

- Communicate information and opinions in a form the patient can understand;
- Allow the patient sufficient time to make a decision—a patient should be encouraged to reflect on opinions, ask more questions and consult with family, a friend or advisor.

Where requested, a patient should be assisted in seeking other medical opinions;

- Repeat key information to help the patient understand and remember it;
- Give written information or use diagrams where appropriate;
- Pay attention to the patient's responses to help identify what has or has not been understood; and
- Use a competent interpreter when the patient is not fluent in English.

It may be necessary to convey information in more than one session.

(See further regarding communication: NHMRC, Communicating with Patients: Advice for Medical Practitioners).

When information can be withheld

Information can be withheld in limited circumstances, namely:

- An emergency, when immediate intervention is necessary to preserve life or prevent serious harm and it is not possible to provide information;
- Where the patient expressly directs the medical practitioner to make the decisions, and does not want the offered information (legally known as a 'waiver'). Even in this case, the medical practitioner should give the patient basic information about the illness and the proposed intervention; and
- Where the medical practitioner judges on reasonable grounds that the patient's physical or mental health might be seriously harmed by the information (known as therapeutic privilege).

AMA *IFC Guidelines* (in relation to fees and charges for inpatient medical services)

Informed financial consent means the dialogue between the medical practitioner and patient so that the patient understands:

- The potential fee for the medical procedure;
- The potential fee associated with other medical providers involved in the procedure, including anaesthetists and assistant surgeons; and
- The potential rebate for the services from Medicare and/or the patient's private health insurer.

As a consequence of this dialogue, the patient would be expected to have an estimate in writing of what his or her out-of-pocket costs might be, subject to variations in fee estimates due to unforeseen circumstances.[63]

IFC and Australia's health care system

In-hospital services

In Australia, Medicare enables all citizens and permanent residents to access inpatient treatment in a public hospital as a public patient.[64] However, the cost of some treatments may not be covered by Medicare, or patients may choose to be treated as private patients, incurring costs for treatment, and raising the important issue of IFC.

Medicare covers 75 per cent of the Medicare Benefits Schedule (MBS) fee for services and procedures for private patients, whether they are treated in a public or private hospital (although hospital accommodation and items such as theatre fees and medicines are not covered, and doctors may charge fees higher than the MBS fee).[65] The extent to which a private patient incurs out-of-pocket costs will then depend on the individual's insurance policy.

Health insurers offer both 'no gap' schemes (in which there may be no out-of-pocket expenses) and 'known gap' schemes (in which the patient's out-of-pocket expenses are capped at an agreed amount for each procedure). Even with a no gap policy, patients can be left out-of-pocket, or with more expenses than they expected. This is for a variety of reasons including that their preferred medical practitioner may not participate in their health insurers' gap scheme. Patients who receive treatment from a medical practitioner who does not participate in any form of gap scheme will be charged all costs above the MBS fee. Further, the medical tests and treatments recommended by a patient's medical practitioner may not attract a private health insurance rebate. For example, private health funds do not cover radiotherapy because it is an outpatient procedure. Patients who wish to be treated as a private patient for radiotherapy must therefore pay the gap between the cost of treatment and the Medicare rebate.[66]

Studies indicate that about 85 per cent of private patients in Australia have 'no gap' cover[67] and about 89 per cent of private in-hospital medical services are provided without a gap fee.[68] It is not clear to what extent theses figure are accurate for persons receiving treatment for cancer.

An issue affecting both public and private cancer patients is that some recommended tests and treatments do not attract a Medicare rebate. For example, breast MRIs, bone mineral density scans, oncotype DX gene assay tests and PET scans are recommended for women being treated for breast cancer but are not currently covered by Medicare.[69] Similarly, new cancer drugs may be approved for use by Australia's Therapeutic Goods Administration, and be prescribed by oncologists, but not receive immediate listing on the Pharmaceutical Benefits Scheme (PBS). Patients wishing to use such treatments must pay their cost in full, which can reach tens of thousands of dollars.[70]

Where a patient is involved in a clinical trial, the direct costs of research (such as treatment, tests and patient check-ups), are paid for by the organisation conducting the research. However, depending on the particular trial, participants may face out-of-pocket costs for travel and accommodation.[71]

Outpatient services

As noted, out-of-pocket costs can be an issue for cancer patients outside of the hospital system. Visits to a GP are free if the doctor 'bulk bills' (accepting the MBS fee as full payment).[72] However, many GPs charge a higher consultation fee and Medicare only covers 85 per cent of the MBS fee for specialists.[73] In 2012-13, about 81 per cent of GP consultations were bulk billed.[74]

Patients also need to pay for the prescription and over-the-counter medicines they receive outside of hospital. Most prescription medicines are subsidised under the PBS, with further discounts available to concession card holders.[75] However, as noted, medical practitioners may also prescribe non-PBS medicines, which can be costly. Medical practitioners may recommend complementary treatments such as massage or acupuncture. These can be costly, although individuals with health insurance may receive a rebate. Medicare rebates are also available for a limited range of complementary therapies.[76]

Government subsidies and rebates

Patients' out-of-pocket medical expenses can be minimised by two Federal government subsidies and rebates—the Medicare Safety Net and the PBS Safety Net.[77] Eligibility is determined by an individual's financial situation and their overall health care expenses. Individuals who qualify for a government Health Care Card are also entitled to cheaper PBS medicines and have a lower threshold for accessing the Medicare Safety Net.[78] A net medical expenses tax offset was introduced in 2013 but is being phased out.[79]

Barriers to informed consent

There are many barriers that can inhibit the process of informed decision-making in cancer care, at the patient level, the practitioner level, and the organisational and systemic levels. For example, studies report that patients: feel intimidated, stressed or under time pressure during consultations;[80] do not feel empowered to raise questions;[81] and find it more difficult to understand treatment information if they are distressed or depressed.[82]

Obtaining informed consent requires that medical practitioners be able to assess a patient's level of comprehension and explain complex information clearly. It can be difficult for practitioners to determine what information should be shared with patients, particularly given that patients have varying levels of desire to know about risks.[83] Patients have varying levels of health literacy and certain groups may have higher communication needs which are not met by standard processes (for example, culturally and linguistically diverse communities, individuals from low socio-economic backgrounds, Aboriginal and Torres Strait Islanders or persons with disabilities).[84] Further, legal and professional requirements regarding the provision of information may not be well understood by doctors.[85]

Box C:
Factors affecting whether patients have out-of-pocket costs

In Australia, the degree to which a patient faces out-of-pocket medical costs for cancer treatment is impacted by a range of factors. Among these are:

- Whether an inpatient is treated as a public patient (under Medicare) or privately (using private health insurance);
- The type of treatment received, including whether these attract Medicare and/or private health insurance rebates;
- The type of health insurance held, if any;
- Whether the treating doctors participate in no-gap or known gap insurance schemes;
- A patient's eligibility for government subsidies and rebates;
- Whether medications and other medical items need to be obtained outside of hospital;
- For outpatient services, whether a doctor 'bulk bills'.

At a broader level, consultations may be too short for adequate doctor-patient discussion; related to this, remuneration systems can incentivise shorter consultations.[86] Organisational barriers include poor communication systems or supporting infrastructure within hospitals and health systems,[87] making it harder, for example, for patients to obtain accurate information when several doctors are involved in their treatment.

Additionally, the doctor who explains the medical procedure at a hospital may not be the person who performs it, with the task of obtaining informed consent to treatment often delegated to junior doctors.[88]

In addition to providing information orally to patients, medical practitioners may provide written information such as brochures or books or use formats such as DVDs, audio recordings and interactive decision-aids.[89] Many patients also conduct their own research in books or the internet.[90] While such resources can be extremely helpful for patients, they can also be lacking, for example, omitting relevant data or failing to provide a balanced view of the effectiveness of different treatments.[91] Consent forms are also often used to provide more detailed information to patients about their treatment (as well as to legally protect the medical practitioner and/or hospital), however, these are often poorly understood by patients.[92] Information can be particularly difficult to comprehend for patients involved in clinical trials as they are required to read lengthy and often complex patient information and consent forms.[93]

Underlying the barriers to informed decision-making appears to be a disconnect between the way in which some medical practitioners understand the purpose of informed consent processes, as compared with the way in which patients understand the purpose of informed consent processes. Research suggests that many patients see informed consent as a legal process undertaken by doctors to protect themselves from liability, rather than as an exercise in patient autonomy and choice.[94] The use of the word 'consenting' by some doctors as a verb to refer to obtaining informed consent –may reinforce this perception (and has been described as a contradiction in terms[95]).

There are also barriers in relation to obtaining IFC to cancer treatments, including difficulties in the provision of accurate estimates of costs prior to treatment. This can be due to factors such as:

- The involvement of multiple practitioners in providing treatment, in addition to the primary medical practitioner (for example, a surgeon, anaesthetist and oncologist). Specialists may set their own fees, which may not be communicated to the primary provider;
- Short lead times between the patient's decision to undertake treatment and the treatment itself. This can leave 'third party' providers such as anaesthetists with insufficient time to obtain IFC;
- The complexity of some health insurance policies, making it difficult for both patients and doctors to determine the available rebate;[96] and
- The complexity and length of treating diseases like cancer which can make it difficult for doctors to predict all the treatments, and associated costs, that may be involved.[97]

Further, there is evidence that some medical practitioners, including oncologists, feel uncomfortable about discussing treatment costs with their patients.[98]

McCabe Centre patient survey and focus groups: design overview

To help inform this report, the McCabe Centre conducted an online survey, as well as two focus groups, with Victorian cancer patients. The aim of this stakeholder consultation was to obtain patient feedback regarding:

- How well legally and medically relevant information was provided by medical practitioners to participants about their cancer diagnosis and treatment;
- Whether participants felt able to make informed decisions about their treatment; and
- The barriers that inhibited or prevented participants from understanding the information provided to them.

In both the online survey and focus groups, patients were asked questions about the information they were given by their medical practitioners regarding their diagnosis and treatment. The questions were designed to gauge whether patients had been given information consistently with legal and professional standards. Participants were asked, for example, whether they felt that they received enough information about the nature of their cancer; tests required for their diagnosis; the expected benefits of the proposed treatment; any risks or side-effects; and other treatment options.

Participants were also asked if they felt that they understood the information provided.

The survey asked participants 'yes/no' style questions, but also provided 'comment' boxes, allowing individuals to explain their experiences in more detail and provide general comments about how the consultations with their medical practitioners could have been improved. Participation in the survey was anonymous to encourage candid responses. The focus groups asked similar questions, but allowed us to explore participants' experiences in greater detail than was possible in the survey.

The survey was developed with the support of CCV's Centre for Behavioural Research in Cancer. Prior to distribution, the survey was reviewed by our Expert Working Group (which included medical, health and legal experts), approved by CCV's Human Research Ethics Committee, and tested by a small group of persons who had been treated for cancer.

Eligibility for the survey and focus groups was limited to persons who had received a cancer diagnosis within two years of the date they completed the survey or attended the focus group, and who received their medical care in Victoria.

Our survey was completed by 113 persons who were diagnosed with cancer, 104 of whom had received treatment. Seventy-three participants (65 per cent) had breast cancer, ten prostate cancer (9 per cent) and six bowel cancer (5 per cent). The remaining respondents had a range of cancers, among them, bone, bladder, brain, cervical, kidney, liver, lung, skin, throat and thyroid.

Individuals were invited to participate in the survey through a range of means including email lists, newsletters and social media. We are particularly grateful for the assistance of the Breast Cancer Network Australia (BCNA) and the Prostate Cancer Foundation of Australia (PCFA) for their assistance in advertising the survey to potential respondents. The large number of participants with breast cancer, and to a lesser extent, prostate cancer, reflected the assistance of the BCNA and PCFA in recruiting.

Forty-four of 104 respondents were treated as private patients, 40 as public patients, and 20 with a mix of public and private care. Most participants (79 per cent) were between the age of 41 and 70. Eighty-four per cent were female. Sixty-eight per cent lived in metropolitan Melbourne and 32 per cent in regional Victoria.

The focus groups were conducted with the support of an external focus group provider. One group included women who had been treated for breast cancer, the other men who had been treated for prostate cancer (up to ten persons per group, age range 28 – 73 years, with 45 per cent between the age of 51-60).

We selected these cancer groups on the basis that they are both common types of cancer. Also, limiting each group by cancer type and gender helped to foster discussion among participants. Persons were recruited through the BCNA, PCFA and an external recruitment agency. Seventeen participants lived in metropolitan Melbourne and two in regional Victoria. All but two of the participants had private health insurance and were generally treated through the private system.[99]

Due to the relatively small sample size of Victorian patients consulted for this report, and the predominance of respondents with breast or prostate cancer, we do not intend to make claims about how representative the concerns raised by participants in our survey and focus groups are among all Victorian cancer patients.

Patient survey and focus groups: key feedback

The key feedback we received from participants in our survey and focus groups is outlined below. Note that not all participants responded to every question (we have indicated how many responses we received to each question below).

Respondents were able to answer in relation to three medical practitioners for each of the diagnosis and treatment questions. The numeric results provided below relate to the medical practitioner from whom the patient received most information about his or her cancer diagnosis or treatment (smaller numbers of persons responded in relation to second and third medical practitioners). The patient comments are drawn from responses about all three medical practitioners.

Diagnosis

Survey feedback

It was evident from various comments that many patients felt that they received good information about their diagnosis from their medical practitioners.

[My doctor was] very thorough and never rushed and was able to answer any questions I had.

When receiving the diagnosis, whilst I heard information I didn't want to hear, it was information I "needed" to hear. The doctor did this in a very straight forward, no nonsense way.

However, 11 of 104 respondents (10.6 per cent) felt that, *overall*, they did not receive enough relevant information from their medical practitioners about their diagnosis, and 12 of 104 (11.5 per cent) felt that they were not able to understand it.[100] In addition to not receiving enough information overall, a minority of patients felt that they could have been given more information about specific areas:

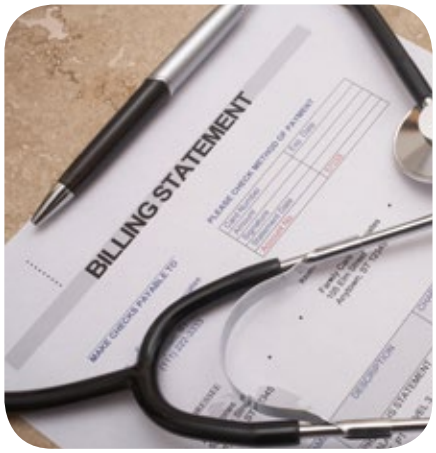


Table 1

Do you feel that you were given enough relevant information about:	Yes	No	Unsure	Preferred not to know	Responses
The nature of your cancer (e.g. type, how advanced)	90	13	8	2	113
Any uncertainties related to your diagnosis (e.g. how far cancer has spread)	79	24	8	1	112
Your prognosis (The likely outcome of your cancer – with or without treatment)	85	18	8	2	113
The tests required for your diagnosis (e.g. biopsy, blood tests)	97	10	6	0	113
Any risks or side-effects associated with these tests, including their likelihood and seriousness? (e.g. pain, scarring)	84	23	5	1	113
Any uncertainties associated with these tests (e.g. reliability of tests)	71	27	14	1	113

A minority of respondents also indicated that they did not understand information they were given about specific areas:

Table 2

Do you feel that you understood the information you were given about:	Yes	No	Unsure	No, but preferred not to understand
Your diagnosis	95	12	5	1
Your prognosis (the likely outcome of your cancer)	81	18	9	5
The tests required for your diagnosis	91	12	9	1
Any risks or side-effects associated with these tests	78	25	9	1

Comments included:

I read a lot on the web and learned a lot from BCNA booklets. So I felt well informed, but not so much from the doctor.

Several persons found that it was difficult to absorb the information provided due to anxiety or shock:

I don't feel that I was in a fit state to fully take in some of the information. Now, after treatment, and after reading most of the information again, it's surprising just what did not register. I think this was because most of the information was written and my level of concentration low.

My initial diagnosis was with the surgeon … I was still probably in shock and missed information I was being told.

Nine of 112 respondents indicated that were not encouraged or did not have an opportunity to ask questions about their diagnosis and associated tests.[101] Complaints included the following:

I often felt I was asking too many questions, so I would ask online cancer patients instead.

I felt rushed and always left from each appointment like I was missing some vital information.

The doctor was always running late so I often felt like I was wasting her time.

Several respondents also identified that feelings of being overwhelmed or in shock made it difficult for them to know what questions to ask:

My diagnosis was on the same day as the tests. It was fairly overwhelming, so I did not know what to ask for a few days.

At my initial meeting with the surgeon I was still numb and in denial at receiving the diagnosis and unable to think clearly about what questions I needed to ask …

Twenty-four of 113 respondents felt that some important information was not given to them about their diagnostic tests.[102] Complaints included that:

I was given inadequate warning of pain and bruising from transperineal saturation biopsy. I was not warned it was a 24 needle biopsy—I expected 12.

If I knew [about the pain of the biopsy], I wouldn't have gone through that biopsy. It's invasive and I am scarred from that experience.

At no stage did anyone inform me that a mammogram and ultrasound were not sufficient for the dense breast tissue of my breasts. I should have received an MRI. Probably due to cost, this was never offered.

Five persons indicated that they would not have had the same tests if they had been given the information they felt was missing.[103]

Nineteen of 112 respondents reported that they experienced side-effects or harm from their diagnostic tests that they were not warned about.[104] Reported side-effects or harm (ranging from minor to severe) included:

- Pain: from biopsies; lymph node removal; injection of dye for x-ray;
- Bruising from biopsies;
- Scarring;
- Blurred vision from an MRI;
- Larynx granuloma (inflammation);
- Pelvic floor spasms, preventing the persons from cycling for eight weeks (their main mode of transport); and
- Pneumothorax (a collapsed lung) from a biopsy;

These side-effects or harm (of which some respondents had multiple) were short-term for 16 persons (lasting days or weeks), but lasted several months for five people and were ongoing for 12.

Forty-three of 112 respondents felt that the consultations about their cancer diagnosis and associated tests could have been improved.[105] Suggestions included providing more information:

- About what is involved in biopsies and possible side-effects or harm;
- About side-effects from various treatments;
- About benefits and risks of nuclear scans;
- About support services such as patient support groups; and
- In writing (although others received too much).

Some respondents suggested that medical practitioners needed to:

- Generally be more informative, patient and allow questions to be asked;
- Provide more consistent information (several respondents had medical practitioners who provided contradictory information).
- Provide better explanations about PSA tests;
- Have more empathy with the patient; and
- Improve their communication skills.

Further suggestions for improvements in consultation processes included:

- Providing the patient's cancer diagnosis in person rather than over the phone;
- Advising the patient to bring a support person (such as a family member) to a consult where they would be told that they have cancer;
- Providing more time to discuss issues and concerns (one of the most common complaints) and to absorb the information;
- Providing the patient with their prognosis earlier (if medically possible);
- Providing a greater number of consultations;
- Conducting a follow-up consultation to discuss the diagnosis after the patient has had an opportunity to process the initial information and get over their shock (rather than proceeding straight to treatment); and
- Not holding consultations immediately after major tests such as bone marrow biopsies where the patient was in pain, and too 'out of it to understand what was being explained'.

Suggestions for systemic improvements, included:

- Reducing long wait times at the medical centre; and
- Providing all breast cancer patients with breast care nurses (which some respondents found very helpful).

I had a mammogram on the Monday and saw the specialist on the Wednesday expecting he would tell me I needed a biopsy. Instead I was on my lunch break with no one and was told I had breast cancer.

[It was] very confusing. [There were] so many doctors and different opinions.

Focus group feedback

As with the survey, focus groups participants generally felt that *overall* they received good information from their doctors about their cancer diagnosis and generally understood the information provided. Most, however, still had complaints or suggestions for improvement.

The key feedback from both the male and female groups was that many felt overwhelmed by their cancer diagnosis, which made it challenging to understand the information provided. People described 'being in shock' or 'in a fog' and feeling that 'everything was a blur' or like 'being on a fast train.'

Interestingly, generally the female participants felt that they received too much information about their cancer diagnosis, which contributed to their feeling of being overloaded and overwhelmed. This was in part because some received detailed written information from support agencies in addition to the information provided by their doctors.

To some degree I think I got information overload. It was just all thrown at me … and I didn't know where my head was.

One comment was that it would have been useful to have the right information at the right time rather than being overwhelmed with too much information all at once.

A related concern was that some women felt that they were given too much generic information about breast cancer, rather than clear, simple information that was tailored to their own situation. A key challenge was that there was often little time to digest the information provided about their diagnosis, as decisions needed to be made quickly about treatment.

At the time of diagnosis, most women had attended a clinic alone for further tests due to a lump or unclear mammogram result and were not expecting to spend a day having multiple tests, medical imaging and biopsies, culminating in a cancer diagnosis on the same day. Several commented that it would have been helpful to have had a support person with them to help explain and/or discuss the information provided (such as a partner or breast care nurse).

The information went straight over my head. After the biopsy, I just wasn't good then. From then on my partner came with me and he wrote notes about everything, which was good for me because nothing went in.

I was never referred to a breast care nurse and I think it would've benefited me to debrief all that information. There was so much information … Looking back it would've been great if I had someone from Jane McGrath Foundation, Cancer Council—someone that could spend three hours with me to go through it all again, to repeat it and personalise it.

A specific complaint from one participant was that more information was needed, prior to testing, about the pain associated with mammograms as well as any potential side effects (for example, from exposure to radiation).

In contrast to the women's group, many of the male participants initially felt that they did not receive enough information about their cancer diagnosis. When explored, it appeared that considerable information was provided, but many of the men did not feel that they had enough time during the initial diagnosis consultation to ask questions and fully understand their diagnosis and prognosis.

He is going through the process, gives you the diagnosis, the information, a lot of information, but then in five minutes you're out the door. Pretty much you've got cancer and a box of books.

Similarly to the women, the men felt overwhelmed and 'out of control' when they received their cancer diagnosis, making it difficult for them to understand or retain information or to know what questions to ask during the consultation.

When you first get diagnosed you start thinking about a lot of other things other than what you have. It's very hard. Sometimes they're telling you very quickly what might be happening, what will happen. You've got to take all that in—sometimes too much information too quickly.

As soon as the doctor says 'you've got cancer', you don't really listen to most of what they say.

Helpfully, the time between diagnosis and treatment was considerably longer for most of the men (as compared to the women's group who had more aggressive cancers), allowing more time to discuss, digest and understand the information given and to seek multiple medical opinions (if this was felt to be necessary).

Some men felt that their initial diagnosis lacked clarity, with the meaning of PSA test results being unclear, partly due to doctors 'disagreeing' with each other about how PSA results should be interpreted. Men also commented that it would have been helpful to have a support person present and consultations to help explain and/or discuss the information. Several commented that speaking to someone from a prostate cancer support group helped in terms of processing the information they received.

Treatment

Survey feedback

Of the 104 participants who received treatment, most received surgery (54), chemotherapy (48), hormone therapy (35) and/or radiotherapy (22).[106] As with information regarding diagnosis, it was evident from various comments received that many patients felt that they received good information about their treatment from their doctors.

However, 12 of 104 respondents (11.5 per cent) felt that, *overall*, they did not receive enough relevant information from their cancer doctors about their treatment, and 10 of 103 (9.7 per cent) felt that they did not understand it.[107] Twelve of 102 respondents (11.8 per cent) indicated that they did not receive the information they needed from their doctors to make an informed decision about their treatment.[108]

In addition to not receiving enough information overall, a minority of participants felt that they could have been given more information about specific areas:

Table 3

Do you feel that you were given enough relevant information prior to treatment about:	Yes	No	Unsure	Preferred not to know	Responses
What it would involve	90	11	3	0	104
The expected benefits or outcome of the treatment	94	7	3	0	104
Any uncertainties about the expected outcome of the treatment (eg likelihood of success)	72	25	5	1	103
Any risks associated with treatment, including their likelihood and seriousness	79	19	4	1	103
Possible short-term side-effects of the treatment, including their likelihood and seriousness	82	17	4	1	104
Possible long-term side-effects of the treatment, including their likelihood and seriousness	72	25	5	2	104
Any significant long-term physical, emotional, mental, social, sexual, financial or other outcomes associated with the treatment	58	40	5	1	104
The time involved in having the treatment	92	8	4	0	104
How long it should take to recover	65	27	10	0	102
Other available treatment options, and their risks and benefits	52	40	10	1	103
The option of not having treatment	56	39	5	3	103
The doctor who would conduct the treatment and their level of experience with that type of treatment (eg surgery)	81	14	7	1	103

Regarding the option of not having treatment, people commented:

Having no treatment wasn't ever an option. I wasn't asked if I wanted to go ahead with it, it was just a given that I would do it.

Eight of 104 respondents indicated that they did not understand the information they were given about their treatment.[109] As with information regarding diagnosis, some respondents felt overwhelmed by the information provided:

It's not about understanding, it's about information overload.

Once I heard the word cancer I could not hear or understand what the doctor was saying to me.

One person indicated that they were also in shock when told about the cost of treatment, which impacted on their ability to understand the information provided.

Most respondents (97 of 104) felt that information was provided in a form that they could understand –typically an oral explanation (100), and often including diagrams (62) and written information (74).[110] However, 26 of 103 respondents indicated that it was not repeated to help them understand and remember it[111] and nine of 104 that it was not appropriate to their personal circumstances.[112] Seventy-six of 104 persons signed a consent form[113] —four persons indicated that they did not understand it.[114]

Ten of 104 participants indicated that their doctor did not encourage them to ask questions[115] and seven of 102 that their doctors did not answer their questions as fully as possible.[116] Comments included:

[My doctor] wasn't too fond of the extra questions I asked.

[My doctor was] evasive. At times dismissive.

Thirty of 103 respondents indicated that their doctor did not actively encourage them to talk to a family member, friend or other trusted advisor about their treatment decision.[117]

Thirteen of 104 respondents felt that they did not have enough time to make a decision:[118]

There was a hurry to start treatment so the whole process was a blur.

Twelve of 104 respondents indicated that their doctor did not confirm that they understood the information they were given.[119] Only nine of 103 respondents indicated that their doctors encouraged them to get a second medical opinion.[120]

In terms of making a decision about treatment, 43 of 104 persons reported that they just followed their doctors' advice, and 11 that their doctor made the decision with their consent. Ten indicated that they made their own decision, and 33 that they made their decision jointly with their doctor. Five persons felt pressured into having a particular treatment.

Twenty respondents felt that they were not given important information about their treatment.[121] Respondents reported that information was not provided, or more information was needed, about

- Side effects, including:
  - The severity of some side effects;
  - The full side-effects of chemotherapy;
  - Mental and sexual and side-effects of various treatments;
  - The side-effects of lymph node removal;
  - Radiation permanently shrinking the patient's affected breast;
  - Radiation affecting the patient's skin, affecting future reconstruction options;

Table 4

Side effects experienced by patients, which they were not warned about prior to treatment	
Severe reaction to a cancer drug lasting two months	Ongoing side-effects from hormone therapy
Tiredness and random aches	Fatigue, including chronic fatigue
Nausea	Severe weight loss
Painful scarring	Heart issues and high blood pressure
Pain and restricted movement, including breathing, from a tissue expander (used during breast construction following a mastectomy)	Long-term body aches, depression, menopausal symptoms and hormonal problems
Pain from laying on a hard table during radiotherapy	Axillary web syndrome (cording) in arm from surgery
Heavy menstruation	Blood loss
Changes in thyroxine levels	Lymphedema
Radiation burns	Change in taste buds
Diverticulitis (digestive disorder)	Bowel obstruction
Blood clot in lung	Blood clot in arm
Dry skin	Neutropenia
Reduced sexual responsiveness;	Emotional problems
An allergic reaction	Infection
Damage to vocal cords	A urinary tract infection
Neuropathy (nerve pain) from chemotherapy	Pain and numbness in mastectomy area
Loss of appetite	severe bone pain from a cancer drug
Anxiety	

- Additional treatment options, including:
  - Options with regard to types of surgery;
  - The availability of a surgical fertility preservation procedure;[122]
  - Treatment outcomes, including that:
  - Lumpectomy margins may not come back clear;
  - The patient could lose nearly all of their bowel; and
- Treatment recovery, including:
  - The length of time it would be unsafe to lift heavy objects after an operation;
  - The need to have physiotherapy once recovered and active treatment was over, to help avoid issues with pain and restriction of movement.

Four persons indicated that if given the information they regarded as important they would not have had the same treatment,[123] while another would have considered other options.

Thirty-five of 102 respondents indicated that they experienced side-effects or harm from treatment that they were *not* told about prior to treatment.[124] See Table 4 below for more detail.

The harm or side-effects (of which some persons had multiple) were minor for 10 persons, moderate for 25 and severe for 11, and short-term for eight, medium-term for nine and ongoing for 29.

[The doctor said] you'll be fine... No side-effects really he said. 3 months and counting of side- effects, hospitalisation and severe chest pains... None of this was spoken of.

The intensity and duration of fatigue was not made clear. Other side effects were also understated, Emotional aspects were ignored.

I feel I have been over medicated … one particular medication caused lots of problems. I've been scared and nervous at my lack knowledge as to what was happening to my own body.

Twenty-three of 104 respondents indicated that their consultations regarding treatment options could have been improved.[125] Aside from the types of complaints raised above, participants made varied comments to the effect that information and communication could have been improved through:

- More information about side-effects – type, effect, severity, how to treat;
- More open discussion about treatment options and the likelihood of success or failure;
- More opportunity to ask questions;
- More attention being given to patient concerns;
- Provision of more personalised information;
- Improving the written information sheet given to the patient;
- Taking patients more seriously and listening to their concerns – doctors needed to remember that 'a human was involved';
- Doctors having greater 'understanding of the significant emotional and social impact of the diagnosis';
- Doctors being more forthright in providing their medical opinion, rather than saying it was the patient's choice;
- Specialists considering the 'whole picture', rather than just their own field (i.e. having a proper understanding of other treatments and their effects);
- Recording the consultation, as the patient forgot much of what they were told in the consultation;
- The provision of information by the doctor about patient support groups;
- Active encouragement from the doctor for the patient to seek a second medical opinion;

Respondents also commented that consultation procedures around treatment options could have been improved through:

- Consultations being longer to ensure patients do not feel rushed;
- Waiting times for specialists, and treatment, being shorter (a comment made by several public patients);
- For several patients with breast cancer, having breast care nurses in consultations and involved throughout the treatment process (to, among other things, help the patients' understand the information they were provided with);
- Providing more time between diagnosis and the commencement of treatment, where possible, to allow time for the diagnosis to sink in, discussions with family, and informed decisions to be made;
- Doctors encouraging patients to have a partner or friend attend the consultations (a number of respondents reported that having a support person was extremely helpful);
- Improved continuity of care for public patients so that they do not have to repeat their medical history and explain the side-effects they are experiencing to a number of different oncologists (one patient commented that they would have liked to have been able to see the same doctor throughout their treatment even if this meant paying);
- Having a 'go to' person or care co-ordinator who could help to advise the patient throughout their care. In this regard, one woman with breast cancer commented that:

An invaluable part of the medical team was the breast nurse coordinator. She provided information throughout the time of diagnosis to the end of treatment. She liaised with doctors, nurses and the hospital and coordinated the whole process. She was the one constant who followed my individual progress.

Focus group feedback

As with the information provided about diagnosis, most focus group participants felt that they were generally given good information by their doctors about treatment, were able to understand it, and ultimately make an informed decision about treatment. Again, however, most still had specific complaints or suggestions for improvement.

Participants in the women's group generally indicated that they were presented with a treatment plan by their doctors, outlining what the doctors considered the best approach to treat their particular type of breast cancer ((surgery (lumpectomy or mastectomy and possible reconstruction), chemotherapy and/or radiotherapy and possibly ongoing hormone treatment)). None of the women were provided with treatment options or given the option of no treatment.

The women's group raised a number of concerns including that some received too little information about:

- Possible side-effects from treatment including hormone therapy;
- How to deal with side effects from treatments including chemotherapy and hormone therapy (such as managing weight gain from hormone treatment, emotional impacts from treatment);
- Treatment options, such as a different types of drug or the type of surgery. One person complained that 'you're led to believe you have to have it no questions asked' when there were in fact other options;
- Realistic recovery times;
- Options for reconstructive breast surgery following cancer treatment, the likely result, as well as the risks of certain types of procedures (several women reported being unhappy with the outcome of their breast reconstructions and one reported having severe nerve pain).

Another issue (which equally affected the men) was the difficulty of understanding the medical terminology used by doctors and in written materials.

I think the information for me was worded in a foreign language. I would always go in and say 'I need translation'. It's medical terms of where it is, how deep it is, what it is, estrogen, this and that. It's like you're actually needing to learn a new language specifically connected to breast cancer.

A challenge for many in the women's group was that they needed to commence treatment very quickly. This meant that they felt that they had little choice but to follow their doctors' suggested treatment plan (although most were happy to do so—indeed, some did not want all the information they received, preferring just to be told what they needed to do). One participant described it as like being on a 'really fast train'. Concerns were also raised about receiving conflicting information from doctors.

As with the women's group, most men believed that they received good information and were able to understand (often after much further research and reflection). Unlike the women, who were generally presented with a treatment plan, the men were generally given treatment options and literature by their medical practitioners and told to go away and think about it and make their own decision. This was likely due to the men having more time to make a decision (their cancers being less aggressive) and/or because more treatment options were open to them.

Various complaints were raised by male participants, including regarding:

- Being given conflicting information by doctors about the best treatment for prostate cancer (for example, whether to have standard surgery, robotic surgery, brachytherapy) and the difficulty of assessing the pros and cons of each option;
- Needing more information about what they could expect in terms of the severity, duration and impact of possible side-effects such as incontinence and erectile dysfunction;
- Not being warned about particular side-effects or possible complications. One participant had a numb leg for 12 months following surgery, another issues with their knee, and one person was not warned about the pain and inconvenience of wearing a catheter after surgery;
- Being given information about possible erectile dysfunction from female nurses, who it was felt could not fully understand the nature or impact of this issue;
- Doctors being too busy ('they've got five-ten minutes and you're out the door'). Some commented that they needed longer consultations to properly discuss the information they were given;
- The cost of doctors' consultations (making it unfeasible for some to have sufficient follow-up appointments to discuss their questions);
- Too little information being provided about what dietary changes (if any) could assist their cancer treatment.

As with the women, many of the men were given written information from their doctors to help them understand their treatment options. However, some found better information in books provided by support groups. Many of the participants also felt it necessary to supplement the information they received from their doctors by talking to men in support groups, family or friends who had had prostate cancer, or by conducting internet research. A number of men found it difficult to decide on the best treatment option and would have preferred that their doctors were more forthright in recommending a specific treatment path.

Out-of-pocket costs

Survey feedback

Sixty-five of 102 respondents to the survey had private health insurance while being treated for cancer. Forty-four of 104 were treated as private patients, 40 as public patients (under Medicare), and 20 with a mix of public and private care. Forty-two of 64 respondents with private health insurance reported that their hospital doctors participated in their insurers' 'no gap' or 'known gap' schemes—meaning that they should not have been charged for treatment or their fees should have been capped at an agreed amount).[126] A majority of patients' GPs also bulk-billed.

Eighty-two of 104 respondents reported that they had out-of-pocket *medical* costs associated with their diagnosis or treatment (costs paid by the patient rather than Medicare or their health insurer). Overall, 36 of 103 respondents reported that they did *not* receive enough information from their doctors about their out-of-pocket medical costs.[127]

Table 5 below shows the number of respondents who had out-of-pocket costs in relation to the categories included in the survey, as well as the range of costs experienced (as estimated by patients).

Estimated total out-of-pocket costs for diagnosis and/or treatment ranged from $200 to $30 000. Thirty-five patients reporting having out-of-pocket costs of $5000 or more, and 17 of $10 000 or more.

Thirty-seven respondents of 82 respondents who had out-of-pocket medical costs indicated that some or all of these costs were unexpected.[128]

Costs that were nominated as being unexpected for some patients included: surgery (due to overstatement of Medicare/health insurance rebate by surgeon), chemotherapy drugs, radiotherapy, oncologist and other doctors' consultation fees, anaesthetist fees, mammograms, biopsies, CT scans, MRIs, ultrasounds, pathology tests, medications, physiotherapy, rehabilitation costs, psychology and 'gap' amounts in general. Participants' total unexpected costs ranged from $200 to $10 000-$20 000.

[My] large out of pocket costs for pathology … were a surprise as the hospital did not have an agreement with NIB and Medicare and NIB left a very large gap. This was not explained …

The surgeon booked the medical radiologist, so I would have expected the cost to be explained.

Four of 56 respondents indicated that had they been told about their out-of-pocket costs upfront, they may have chosen different tests or treatment.[129] Six of 43 respondents who were treated privately also indicated that they would have chosen to be treated as a public patient if they had been told about these costs.[130]

However, several persons commented that they knew they faced out-of-pocket expenses, but felt that they had no choice but to bear these costs:

What choice do you really have? If you need to pay for a service that is better than dying from cancer or infection.

Forty-three of 82 respondents indicated that they were *not* given an estimate in writing of their out-of-pocket medical expenses prior to having any tests, procedures or treatment.[131] Only 15 of 54 respondents reported that where their doctor could not accurately estimate their out-of-pocket costs, they were advised to make further enquiries prior to treatment (for example, by contacting the anaesthetist or health insurer).[132]

Thirty-nine of 80 respondents indicated that the process for informing them about costs could have been improved.[133] Comments from participants included that patients should be given more information about anaesthetist costs and the option of having tests and scans done at a public hospital. Respondents also indicated that they had a need for more written information about costs at the start of treatment and more accurate estimates of refunds that are payable. It was also suggested that all doctors be required to provide a written estimate of fees, rather than it being discretionary. Another complained that they were unable to access information about the costs of alternative to robotic surgery to treat his prostate cancer.

The initial treating surgeon could have explained what the option of being treated as a public patient would have entailed.

The private hospital agreements with different health [insurers] seem to be a bit of a mess to me. [Costs] could be made clear when being admitted (by hospital admissions).

Focus group feedback

All but two of the participants in the focus groups had private health insurance and mostly received their care as private patients. While most private patients were told by their doctors to expect some out-of-pocket medical expenses, few were prepared for the extent of these costs (of up to $25 000).

Among the complaints from female participants were being booked in for blood tests, MRIs and other scans and tests without being told that there would be a charge (of up to $3000 in total). Several women commented that they should have been told upfront that scans such as MRIs were not claimable under their health insurance.

Box D:
What patients found helpful when receiving information:

Both women and men's focus groups found the following elements helpful when receiving information from their doctors about diagnosis and treatment:

- Having a support person present during discussions with doctors (for example, a partner, friend, nurse) to take notes and discuss and/or explain information after the consultation;
- Sufficient time during the consultation for information to be presented, explained and repeated by the doctor and for the patient to ask questions;
- The doctor drawing diagrams to illustrate the discussion;
- A one page personalised summary being provided by the doctor about the patient's own cancer;
- Being able to record discussions with doctors;
- Being able to contact doctors by email or phone after the initial consultation to ask further questions;
- Having a team of health professionals (including a breast care nurse for women) for support, to explain information and to answer questions on an ongoing basis;
- For the men with prostate cancer, the support of a prostate cancer, or other support group, to discuss the information provided by doctors and the experiences of other cancer patients.

Thirty-nine of 80 respondents indicated that the process for informing them about costs could have been improved.

Table 5

What did your out-of-pocket costs relate to?	Total persons with these costs	Estimated range of costs
Hospital Costs	26	$150 – 2 400
Surgery	46	$200 – 20 000
Chemotherapy	8	$100 – —3 000
Radiotherapy	21	$300 – 4 000
Hormone therapy	22	$50 – 1 000
'Targeted' therapy, including antibodies and immune treatment	4	$50 – 10 000
Anaesthetist fees	40	$200 – 3 500
Pharmacy medications	57	$40 – 2 000
Doctors' consultations	54	$100 – 5 000
Mammogram	27	$200 – 600
Pathology tests/blood tests	33	$40 – 5 000
CT scan	34	$60 – 500
X-ray	16	$85 – 1 000
MRI	28	$350 – 2 000
Complementary therapies e.g. massage, dietary supplements (therapies recommended by doctor only)	14	$36 – 500
Other reported costs: vitamins, physiotherapy, psychology, incontinence pads, ultrasound, biopsies, bone scan ($500), goserelin injection (to protect ovaries from chemotherapy)	16	$24 – 1050

Costs associated with diagnosis (especially medical imaging) occurred as part of the initial 'whirlwind' of events in the first day or so of tests and procedures which led to the cancer diagnosis. Many participants reported being sent from one medical test to the next, with no information until the test was being done, about costs and whether or not these costs would be claimable.

Participants with private health insurance in the men's group also reported having unexpected costs such as MRIs. Most were not informed that they had the option of receiving treatment in the public system – although none thought they would have chosen public rather than private treatment. Several were told that it was possible but that the waiting times or lack of continuity of health care (same doctor) would be counterproductive to their health outcomes.

Two participants, however, indicated that if they had known about the cost of robotic surgery upfront (which cost them an extra $5000), they would have opted for standard surgery.

Other complaints included only being given an estimate of cost on the morning before the surgery, and not being told about the cost of physiotherapy (which they believed they could have received for free in the public system).

As with the survey, focus group participants also reported having large non-medical expenses associated with their diagnosis and treatment (of the type reported in the survey).

Complaints

The survey also asked respondents if they had made a complaint about the information they received (or did not receive) from their doctors (where they regarded it as unsatisfactory). Nine of 104 respondents indicated that they had made informal complaints to their doctor, the hospital, a nurse, other hospital staff, or a patient advocate. Several respondents reported obtaining satisfactory outcomes (for example, an apology from their doctor, or information being revised for future patients), but others were unhappy with the responses they received. No complaint proceeded to a more formal level (for example, to the Office of the Health Services Commissioner).
Discussion

Discussion

This report has examined medical practitioners' legal and professional obligations regarding informed consent, including IFC; the barriers that may inhibit or prevent informed consent from being obtained; and Victorian cancer patients' experiences of receiving information about diagnosis and treatment from their medical doctors.

It should be noted that the sample size of Victorian patients consulted for this report was relatively small. Therefore, we do not intend to make claims about how widespread the experiences of the participants in our survey and focus groups are among all Victorian cancer patients. However, our limited sample size has demonstrated that informed consent and IFC are a concern for some patients, and therefore requires the attention of the medical profession.

The legal and professional requirements of doctors regarding informed consent appear to be adequately set out by the NHMRC General Guidelines, *NHMRC Communicating with Patients: Advice for Medical Practitioners* guideline, and the *AMA Informed Financial Consent Guidelines.* These general guidelines appear to be flexible enough to provide effective guidance in a cancer care setting.

The feedback we have received from Victorian cancer patients in both the survey and the focus groups showed that most felt that they received enough relevant information from their doctors about their cancer diagnosis and/or treatment and felt that they understood the information provided. Among participants who received treatment, most felt that they were able to make an informed decision about their treatment.

However, the feedback also showed that many patients felt that they did not receive enough relevant information with regard to specific areas required by law and the professional guidelines, and some did not feel that overall they were able to make an informed decision about treatment. Of particular concern, some patients felt that they did not feel receive enough information about potential side-effects or complications, including long-term outcomes—both from diagnostic tests and/or their treatment. Also, some felt that they did not receive enough information about treatment options other than the doctor's preferred option. Also of particular concern was that a significant number of patients (35 of 102 who responded) experienced side-effects or complications which they indicated they were not warned about prior to treatment.

The feedback also showed that there are a range of barriers that can inhibit or prevent informed consent from being obtained such as patients feeling overwhelmed and in shock from their cancer diagnosis, a perceived lack of time for consultations, and the speed at which some patients progress from receiving a diagnosis to treatment.

It is interesting to note that almost 10% (nine) of 104 participants had actually made a complaint about the information they received (or did not receive) from their doctors; even though some patients were unhappy with the responses they received, no complaint proceeded to a more formal level. This may be due in part to the knowledge, time, resources and effort required to lodge a formal complaint.[134]

Regarding the issue of costs and IFC, feedback from survey participants and focus group attendees echoed findings in other reports[135] which indicate that many cancer patients experience out-of-pocket medical costs, and that these can be significant in some cases.

Feedback indicated that a large majority of participants felt that they received enough information from their doctors about their out-of-pocket medical costs. However, a significant minority reported having out-of-pocket medical costs that were unexpected, in some cases totalling thousands of dollars. This feedback is consistent with findings from the 2014 Senate Community Affairs References Committee report *Out-of-Pocket Costs in Australian Healthcare*, which concluded that practices for obtaining IFC in Australian health care are often inadequate.[136]

Patient feedback also showed that a majority of participants in our survey and focus groups had non-medical costs associated with their treatment, the major cost being loss of income due to missing work.

Recommendations

1. Greater consistency in informed consent processes is required within the medical profession. Overall, many patients reported that they had positive experiences with the informed consent process; many doctors appear to be providing good quality information to patients, resulting in those patients feeling that they were able to make an informed decision. The challenge is therefore to ensure that the good practices adopted by many doctors are implemented across the board.

2. It is beyond the scope of this report to suggest precisely how that might occur in Victoria. However, it seems likely that some doctors require further education or training to improve their knowledge of the purpose of informed consent processes, their professional obligations and best practice in the provision of information to patients. Our review of the literature, and the feedback we received from Victorian patients, highlighted that there can be many reasons that patients may not feel that they were able to make an informed decision, whether due to a lack of information, or barriers such as a lack of time for consultations or patients being in a state of shock. The challenge is to ensure that all doctors are aware of their legal and professional obligations and adopt effective practices to ensure that those obligations are implemented.

3. Regarding costs and IFC we concur with the view of the Senate Community Affairs References Committee that practices for obtaining IFC in Australian health care are often inadequate and that better mechanisms are required 'to ensure patients are fully informed about treatment costs, before initial treatment as well as throughout any follow-up treatment'.[137]

Next steps

1. The McCabe Centre for Law and Cancer will work with CCV's CISS and Clinical Network to provide information and guidance to medical practitioners and consumers to better understand informed consent and IFC principles, processes and requirements.

2. The McCabe Centre, CISS and Clinical Network to review and update CCV's patient rights information.

3. Regarding costs and IFC, a next step in this project may be to review the approach of the doctors, hospitals and medical centres that do have effective IFC mechanisms in place to identify and articulate best practice approaches.

4. CCV's CISS and Pro Bono Legal Service will continue to develop and provide information and to health professionals and patients about common cancer-related non-medical costs and services that can offer support.

THE REGULATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE PRACTITIONERS AND VICTORIAN CANCER CARE

In Australia, a large number of cancer patients use complementary and alternative therapies, usually in conjunction with conventional cancer treatments.[138] While the use of some complementary therapies, like yoga and massage, by cancer patients is safe and may have benefits, there have been several high profile examples in the past decade of unscrupulous providers taking advantage of vulnerable individuals, often charging large sums of money for unproven or dangerous treatments. These cases have highlighted gaps in the regulatory framework for CAM practitioners who are not members of a registered profession. Whereas registered practitioners are governed by professional Boards with powers to discipline and de-register members who fail to meet set professional standards, no such mechanism currently exists in Victoria for unregistered practitioners.

Reform in this area may occur in 2015. After extensive consultation, in 2014 the AHMAC developed a draft National Code of Conduct for health care workers, which includes powers of prohibition, to prevent people from providing a health service for a specified period of time. It is expected that the Code will be considered by state and territory Health Ministers in the first half of 2015. Additionally, the Victorian Government is currently considering introducing a 'negative licensing' scheme, similar to the model first adopted by New South Wales in 2007.

This type of scheme would include powers for an authorised body to discipline or prohibit further practice by unregistered health professionals who breach a statutory Code of Conduct. These proposals are discussed in greater detail below.

This report provides an overview and critical analysis of this issue as well as our recommendations for how such reforms ought to proceed.

The use of CAM in cancer care

The term CAM refers to a diverse group of medical and healthcare practices, products and systems not presently considered to be part of *conventional medicine.*[139] While 'complementary' therapies,[140] as the name suggests, are used together with conventional medicine, 'alternative' treatments are used in place of conventional medicine.[141]

The use of CAM in Australia by cancer patients and survivors appears to be common, although figures on its use vary widely (largely as a result of differences in study design and how CAM therapies are defined). Studies show that anywhere between 17 and 87 per cent of cancer patients use at least one form of CAM therapy while receiving conventional treatment.[142] The most commonly used CAM are dietary supplements, dietary changes, massage and meditation.[143]

Most cancer patients who use CAM therapies do so as an adjunct to conventional cancer treatment (for example, surgery, radiotherapy, chemotherapy, hormone therapy, immunotherapy). This can be for several reasons including to:

- Gain an increased sense of control over treatment regimens;
- Improve physical and emotional well-being;
- Boost the immune system;
- Reduce side-effects of conventional treatment; and
- Improve quality of life.[144]

A small number of individuals also use CAM to try to directly cure the disease or prevent its recurrence.[145]

Evidence regarding effectiveness of complementary and alternative medicine in cancer care

There is some evidence to suggest that, as an adjunct to conventional treatment, some CAM therapies are beneficial in reducing common side-effects of conventional treatment as well as disease symptoms (see Box F).

Box E:
Examples of CAM therapies used by Australian cancer patients and survivors

- *Natural/biological products* — eg, herbal medicines, vitamins, probiotics and special diets;
- *Mind and body medicine* — eg, meditation, yoga, tai chi and hypnotherapy;
- *Manipulative body-based practices* — eg, acupuncture and massage therapy;
- *Energy healing* — eg, magnet and light therapies, qi gong and reiki; and
- *Alternative medical systems* — eg, ayurvedic medicine, traditional Chinese medicine, homeopathy and naturopathy.[146]

Box F:
Examples of benefits of complementary therapies

- Chemotherapy — induced nausea may be relieved by acupuncture and acupressure;
- Cancer-related pain can be reduced by acupuncture, hypnosis, therapeutic touch, and massage;
- Fatigue may be lessened by exercise, therapeutic touch, meditation and relaxation techniques;
- Stress may be reduced, and quality of life improved, by yoga, meditation and exercise; and
- Anxiety and depressive symptoms may be reduced by meditation and relaxation techniques.[147]

Box G:
Cancer Council Australia and COSA positions on CAM

Cancer Council Australia

1. Supports the use of cancer treatments and symptom relief that have been scientifically tested and shown to be safe and effective (whether conventional or CAM);
2. Supports the right of individuals to seek information about CAM therapies, and respects their decision to use them, provided they are not at risk of being harmed;
3. Encourages individuals to make an informed choice when using CAM. This includes asking questions about the efficacy, risks, contraindications and cost of the therapy, and the qualifications of the practitioner;
4. Encourages individuals to discuss their use of CAM with their conventional healthcare providers in order to minimise risk (for example, oncologist, general practitioner, care coordinator); and
5. Encourages healthcare providers to routinely discuss the use of CAM therapies with all cancer patients and survivors, in an open and non-judgemental manner.[156]

COSA

- COSA encourages its members (doctors, nurses, scientists and allied health professionals) to engage in open discussion with their cancer patients regarding CAM, and to 'cautiously support a patient's use of *safe* CAM with uncertain benefits when used in addition to conventional treatment';
- However, COSA advises members to be 'vigilant about potential harms [of CAM], including the impact on the patient's response to conventional medical treatment' and actively discourage patients from using any harmful CAM or from delaying potentially curative treatment;
- When deciding whether to recommend the use of CAM to a patient, COSA advises that members weigh the potential benefits of the treatment against the possible risks, as well as other treatment options (as with all advice about cancer treatment).[157]

While the types of complementary therapies highlighted above are generally safe,[148] there can be risks in using some CAM that cancer patients need to be aware of. For example, natural products such as echinacea, St John's wort, ginseng, and gingko biloba may adversely interact with treatments like chemotherapy or prescription medicines.[149] Indeed, a recent review of the most common complementary medicines inquired about at Melbourne's Peter MacCallum Cancer Centre found that they all had the potential to disturb chemotherapy, radiation therapy or surgery, putting patients at risk.[150] The most common CAM inquired about were fish oil, turmeric, coenzyme Q10, milk thistle, green tea, ginger, lactobacillus (probiotics), liquorice, astragalus and reishi mushroom (all of which are often promoted as dietary supplements).[151]

Probably the largest risk of CAM is that patients may use alternative therapies *in place* of conventional treatment, reducing their chances of remission or cure.[152] It needs to be emphasised that most conventional therapies are evidence-based, having been scientifically tested in clinical trials and shown to be relatively safe and effective for treating cancer, slowing its growth or providing relief from symptoms.[153] By contrast, some alternative therapies, including those that have been promoted to cancer patients by unscrupulous providers—such as extreme diets; very high doses of vitamins and dietary supplements; and oxygen, ozone, water, magnets and microwave treatments—do not have any evidence to support their effectiveness, and may be harmful, even if used as intended.[154] The possibility of harm arising from the use of CAM means that cancer patients should discuss their use of CAM with their doctor; however, only 50 per cent do so.[155]

Cancer Council Australia and Clinical Oncology Society of Australia positions on complementary and alternative medicine

Recognising that CAM are commonly used by cancer patients and survivors, Cancer Council Australia and the Clinical Oncology Society of Australia (COSA) have developed official position statements on their use (Box G)

Regulatory arrangements for registered health practitioners

Australia's National Registration and Accreditation Scheme

Australia has a two-tiered legal framework for the regulation of health practitioners. The most rigorous form of regulation applies to health professionals who are registered under the National Registration and Accreditation Scheme (NRAS). In order to distinguish the different regulatory frameworks for registered and unregistered practitioners the features of the NRAS are outlined here.

The NRAS was established in 2009 by the *Health Practitioner Regulation National Law Act* (the National Law)[158] which came into force on 1 July 2010. Prior to the introduction of the NRAS each state and territory had its own registration scheme[159] however, several professions including Chinese medicine, occupational therapy and radiography were not registered in all jurisdictions.

Fourteen health professions are currently registered under the NRAS, namely:	
Aboriginal and Torres Strait Islander health Practice	Occupational Therapy
Chinese medicine	Optometry
Chiropractic	Osteopathy
Dental Practice	Pharmacy
Medicine	Physiotherapy
Medicinal Radiation Practice	Podiatry
Nursing and Midwifery	Psychology[160]

Box H:
Example of disciplinary action against registered CAM practitioner under the National Law[170]

Chinese Medicine Board of Australia v Lim[171]

Mr Lim, a Chinese Medical Practitioner, treated a young Somalian gentleman known as FF over 12 consultations for a potentially serious bowel condition in Melbourne. Mr Lim admitted professional misconduct for:

- Failing to provide clinically appropriate treatment;
- Failing to refer FF to a medical practitioner or hospital when it became evident FF required such investigation or treatment; and
- Failing to issue receipts, failing to keep proper records, improperly labelling and dispensing herbs to FF, and providing herbs without proper prescription information.

Mr Lim further admitted unprofessional conduct for issuing receipts for a herbal medicine consultation when electrotherapy treatment was provided and failing to disclose a previous complaint when completing his application for registration as an Acupuncturist.

Mr Lim was reprimanded, his registration suspended for 6 months, fined $2000 and ordered to complete 9 supervision sessions. Conditions imposed included:

- Issuing particularised receipts for each Chinese medicine service provided, not employing any students, requiring all staff to wear name badges for identification and providing full and proper details of any Chinese herbal medicine prescriptions.

One of the most significant features of the registration scheme is the authority given to the relevant body to discipline registered practitioners.

Three of these professions—Chinese medicine, osteopathy and chiropractic—are typically regarded as CAM therapies.

The National Law establishes a co-regulatory scheme for the registered professions, which includes enforceable disciplinary and exclusion powers. Each registered profession has a National Board with broad ranging powers to regulate its members and to protect health consumers. The Boards are supported in their role by the Australian Health Practitioner Regulation Agency (AHPRA). Key functions of the National Boards include:[161]

- Setting requirements for registration of practitioners;
- Registration of suitably qualified and competent persons in the profession;
- Developing professional standards, codes of conduct and guidelines;
- Probity checks to determine if a person is suitable to be registered. A person may be found unsuitable to hold registration for a range of reasons including mental impairment, criminal history or the Board's opinion that a person is 'not a fit and proper person' or able to practice 'competently and safely;
- Monitoring of registered practitioners' suitability to practise; and
- Addressing instances of 'unprofessional conduct',[162] 'unsatisfactory professional performance',[163] 'professional misconduct'[164] and 'impairment'[165], as defined in the National Law.

One of the most significant features of the registration scheme is the authority given to the relevant body to discipline registered practitioners. Lesser breaches of professional standards can be dealt with by the National Boards. Cases involving professional misconduct (the most serious breach) must be referred to the relevant state or territory tribunal (in Victoria, the VCAT),[166] which has the power to suspend or cancel a practitioner's registration or place conditions on their practice.[167]

Where a practitioner is deregistered, VCAT can also:

- Disqualify the person from applying for registration as a registered health practitioner for a specified period;
- Prohibit the practitioner from using a protected title (such as 'medical practitioner'); and
- Prohibit the practitioner from providing a specified health service[168] (for example, preventing a psychologist from practising as a 'psychotherapist' or 'counsellor').

An independent review was established on behalf of AHMAC in 2014 to examine the effectiveness of the NRAS and has unearthed issues such as stakeholder dissatisfaction with the complaints and notification process.[169] We have also received feedback from stakeholders that the Boards may have insufficient resources to pursue many practitioners, as these types of proceedings can be extremely lengthy and time-consuming. Broadly speaking, however, the National Law appears to provide adequate powers to protect members of the public from unprofessional, incompetent or impaired practitioners who are members of a registered profession, including registered CAM professions (see example in Box H). The focus of this paper is therefore on the regulatory scheme that applies to *unregistered* CAM practitioners.

Regulatory framework for unregistered practitioners: laws applicable in Victoria

In the absence of a specific regulatory mechanism, unregistered practitioners in Victoria may be subject to different and overlapping legal frameworks, not all of which are directly targeted at health professionals. Most unregistered practitioners belong to voluntary professional associations, which provide varying levels of self-regulation for their members, but unlike the National Law or negative licensing schemes (outlined below), self-regulatory measures are ultimately not enforceable by the courts and practitioners may choose not to join, or may cease membership of, the relevant association to avoid disciplinary procedures. Several of the laws described below apply equally to registered and unregistered practitioners.

However, in the absence of the type of disciplinary powers available to the registered professions, such laws can serve a more significant regulatory function in relation to unregistered practitioners.

Consumer protection law

The Australian Consumer Law (ACL)[172] prohibits certain types of behaviour for persons or corporations engaged in trade or commerce, including health professionals. Unlawful behaviour includes, among other things, engaging in misleading or deceptive conduct, including in relation to goods or services; unconscionable conduct; and unfair terms of contract.[173] Consumer protection law has proved to be a particularly important, although seldom used, tool for regulators against unregistered health practitioners who provide unproven treatments to cancer patients (see Box I).

The ACL is administered and enforced by the Australian Competition and Consumer Commission (ACCC) and each state and territory's consumer protection agency—in Victoria, Consumer Affairs Victoria (CAV).[174]

The ACCC rarely becomes involved in resolving individual consumer disputes, focusing its resources on more substantial breaches that may harm competition between businesses or cause widespread consumer detriment. Individual consumer complaints are more often addressed through state consumer protection agencies. In Victoria, CAV can refer individual complaints to conciliation and mediation, or institute, defend or continue proceedings on behalf of a consumer.[176]

Many breaches of the ACL constitute an offence for which fines of up to $220 000 for an individual, and $1.1 million for a body corporate, can be issued. The regulator can issue public warning notices to inform the public about persons who it reasonably believes have contravened the ACL.[177] Other remedies include the issuing of injunctions—to restrain contraventions of the Act[178] —and substantiation notices—which require a person to provide information to substantiate or support any claim or representation they have made.[179] Individuals who have suffered loss or damage due to a breach of the ACL can make a claim for damages and compensation.[180]

Box I:
Examples of the use of consumer protection and fair trading law[181]

Noone, Director of Consumer Affairs Victoria v Operation Smile (2012)[182]

Operation Smile operated the 'Hope Clinic' in Melbourne, led by Noel Campbell—a dentist who had been deregistered for providing grossly negligent dental treatment by the Dental Practice Board in Victoria, although remained registered in NSW. The Hope Clinic offered various complementary therapies which it represented could treat a wide range of serious illnesses and conditions, including cancer.

Therapies offered by the clinic included:

- 'Tumour destructive therapies': photo-dynamic therapy, radiowave therapy with glucose-blocking agents, ozone therapy, electrotherapy, mild hyperthermia therapy and sonodynamic therapy;
- 'Metabolic support therapies': organic foods, nutritional supplementation with vitamins and amino acids, immune boosting supplements (Chinese herb Astragalus, Japanese reishi and shitake mushrooms);
- Mind-body therapies: meditation and counselling.

Treatments cost patients $3000 or more per week.

In July 2005, the Victorian Health Minister requested that the Victorian Office of the Health Services Commissioner (OHSC) undertake an investigation into the activities of Mr Campbell. A three year investigation by the OHSC found that:

> *The Hope Clinic has targeted extremely vulnerable patients with terminal cancer. These are people who were desperately seeking some hope for their situation and this Inquiry has determined they have been preyed upon by Noel Campbell. Patients paid large amounts of money for treatments which are largely unproven and some were treated in ways that were not conducive to their dignity or comfort.[183]*

The OHSC recommended that CAV investigate possible contraventions of the Victorian *Fair Trading Act 1999* (Vic) (legislation preceding the *Australian Consumer Law and Fair Trading Act 2012* (Vic)). CAV accepted this advice and brought an action against the clinic for engaging in misleading or deceptive conduct.

At trial, Justice Pagone held that the treatments did not have the support of conventional science and, according to conventional science, were of no benefit to cancer sufferers. However, the statements were found not to be misleading or deceptive in their context, being rather 'mere expressions of opinion'.

This decision was overturned by the Victorian Court of Appeal which held that it was misleading or deceptive to claim that:

- The treatments could cure cancer, or reverse, stop or slow its progress;
- Could prolong the life of a person with cancer; and
- That the treatments were supported by generally accepted science and were evidence-based.

The Court ordered that the Hope Clinic, Operation Smile and Mr Campbell:

1. Be restrained from making any representations about the treatments referred to in the Director of Consumer Affair's claim without first obtaining certification from a medical professional that the intended representations are supported by reliable scientific evidence or expert medical opinion and believed to be effective and safe;
2. Provide to customers or potential customers for the services offered or supplied by the Hope Clinic a prescribed notice describing the finding of misleading and deceptive conduct; and
3. Publish a prescribed public notice of misleading conduct in relation to Hope Clinic services on the website for a period of 6 months.

Kristen Every-Miller v Operation Hope & Ors (2012)[184]

In 2011 the widow of a man who underwent treatment by Noel Campbell brought a small claim ($9,999) against Operation Hope and Noel Campbell, for a refund of money paid to Operation Hope for purported cancer treatments, which had no medicinal or therapeutic purpose.[185] These included an aircraft transmitter Noel Campbell sold to Mr Every Miller intended to treat his cancer.

The VCAT member allowed the widow's claim in full, finding that Operation Hope, through Noel Campbell, conducted themselves, in trade or commerce, in a manner that was misleading and deceptive, and that it caused the Every-Millers' loss.

Box I:
Examples of the use of consumer protection and fair trading law (Cont)

Commissioner of Fair Trading, Department of Commerce v Perrett (2007)[186]

Paul Perrett made a series of representations to patients that he could treat various life-threatening conditions including cancer. Mr Perrett was not officially associated with any CAM profession.

Mr Perrett made numerous false claims to patients including that he was a medical doctor, that he had worked at NASA as a biochemist, and that he had successfully treated himself for leukaemia. He promoted a range of bogus therapies including unorthodox ointments and bags of powder, intravenous drips, liquid substances and capsules. Patients were charged up to $4000 for such treatments and in some cases delayed having orthodox cancer treatment. Mr Perrett was prosecuted by the NSW Commissioner for Fair Trading under the *Fair Trading Act 1987* (NSW).

Harrison J, in the NSW Supreme Court, held that Mr Perret had engaged in misleading or deceptive conduct. The Court ordered that Mr Perrett be restrained from representing that he, or the substances supplied by him, could treat or prevent cancer and other serious diseases.

Australian Competition and Consumer Commission v NuEra Health Pty Ltd (in liq) (2007)[187]

NuEra Health promoted products and treatments under the 'Rana System', developed by Paul Rana, which it was claimed could cure cancer and various other serious diseases. NuEra Health also claimed that the Rana System had a scientific basis and would prolong the life of a person suffering cancer. Patients were charged up to $35 000 up front for their treatment. The unproven therapies offered included high doses of vitamins, special diets, coffee enemas, caesium, and ozone therapy, and services such as live blood analysis and thermal imaging.

After a joint investigation with CAV, NuEra Health was prosecuted by the ACCC in the Federal Court under the *Trade Practices Act 1974* (the Commonwealth precursor to the ACL).

Justice Ryan held that NuEra Health had engaged in misleading or deceptive conduct, and made false or misleading representations. The respondents were ordered to refrain from making any further representations about the efficacy and scientific basis of the Rana System. In making this order, Ryan J commented that Mr Rana had 'indiscriminately thrown together, under the aegis of the Rana System, a package of discredited or entirely unproven theories, procedures and nostrums which he has gleaned from populist literature and a range of other sources of widely varying scientific or medical credibility.' Further, he had engaged in 'a consistently cynical and heartless exploitation of cancer victims and their relatives when they were at their most vulnerable'.

Mr Rana was later sentenced to 6 months imprisonment after he failed to abide by the order.

Australian Competition and Consumer Commission v Jones (2011)[188]

Darryl Jones was prosecuted by the ACCC for claiming that his three-step 'Triune Wellness Offensive', which included reducing or eliminating glucose from the diet and taking laetrile, could treat and prevent cancer.

Mr Jones was held to have made misleading representations. An injunction was issued to restrain Mr Jones from making further such claims unless these were backed by written advice from a registered medical practitioner or suitably qualified University medical researcher.

Health complaints entities

All states and territories, including Victoria, have independent statutory health complaints entities, the primary functions of which are the investigation, resolution and conciliation of consumer complaints against health service providers, as well as conducting investigations of health system failures.[189] In New South Wales (NSW), South Australia (SA) and Queensland, where negative licensing schemes have been introduced, this includes the power to prohibit health professions from providing a health service (see below).

The relevant health complaints entity in Victoria is the Office of the Health Services Commissioner (OHSC),[190] established by the *Health Services (Conciliation & Review) Act 1987* (Vic) (HSCR Act). Patients are able to make a complaint where a health provider (whether registered or unregistered) has acted 'unreasonably' in providing a health service.[191] The Commission may either reject a complaint or refer the matter for voluntary conciliation.[192] Thirty-three complaints were made against unregistered health practitioners to the OHSC in 2013/14.[193]

The OHSC offers a useful alternative legal avenue for health consumers, allowing patients to seek remedies from a provider such as an explanation, apology, remedial treatment or compensation, without going to court.[194] However, the OHSC's role is currently limited by its lack of enforceable powers; that is, it lacks the authority to suspend or prohibit a health practitioner from providing a health service, or to place conditions on how that service is provided. These powers would be given to the OHSC (or a similar body) if a negative licensing scheme is adopted in Victoria (see below).

Holding out offences and restrictions on specific acts

The National Law (discussed above in relation to registered practitioners) makes it an offence for unregistered practitioners to hold themselves out to be registered health professionals or to use titles reserved for use by those professions—such as 'medical practitioner', 'radiographer', 'nurse', 'osteopath' or 'Chinese medicine practitioner'.[195] Penalties apply to practitioners who breach these provisions: $30 000 for individuals and $60 000 for corporations.[196]

The National Law also makes it an offence to provide services or procedures that are specifically restricted to certain professions under the National Law (for example, only chiropractors, osteopaths, medical practitioners and physiotherapists may perform manipulations of the spine).[197]

Negligence law and contract

Under the tort of negligence, it is well established that medical practitioners have a duty to 'exercise reasonable care and skill in the provision of professional advice and treatment' to patients, consistent with the standard of an 'ordinary skilled person exercising and professing to have that special skill'.[198] Other health practitioners—including those who are unregistered—similarly owe a duty of care to exercise reasonable care and skill.[199]

Broadly speaking, this means that health practitioners must take reasonable precautions in response to foreseeable risks of harm (unless these risks are insignificant), and ensure that their patients provide informed consent to any treatment.[200] Similar obligations arise in contract law.[201] A plaintiff who can prove negligence on the part of a health practitioner may be entitled to claim damages.

Regulation of CAMs

The focus of this paper is on the regulation of unregistered CAM *practitioners*, rather than the regulatory scheme for complementary and alternative medicines. However, the regulatory scheme for medicines should be briefly mentioned.

In Australia, therapeutic goods, including medicines, are regulated by the *Commonwealth Therapeutic Goods Act 1989* (Cth) (CTGA), which is administered by the Therapeutic Goods Administration (TGA).[202]

The CTGA controls the supply, import, export, manufacture and advertising of goods that are, or are represented as likely to be, for therapeutic use.

Higher risk medicines (prescription medicines, most over-the-counter medicines and some complementary medicines) must be 'registered' on the Australian Register of Therapeutic Goods (ARTG).

These medicines are individually evaluated for quality, safety and effectiveness.[203] Lower risk medicines containing pre-approved, low-risk ingredients that make limited claims regarding effectiveness, can simply be 'listed' on the ARTG (this applies to most complementary medicines).[204]

Some therapeutic goods are exempt from registration or listing under schedule 5 of the Therapeutic Goods Regulations 1990 (Cth). This exemption is relevant to CAM practitioners who make their own therapeutic preparations for patients. Exemptions exist for categories such as homeopathic preparations (that meet certain criteria), starting materials (such as raw Chinese herbs) and medicines that are dispensed or extemporaneously compounded for a person for therapeutic application.[205]

All states and territories including Victoria have acts and regulations that restrict the supply of prescribed drugs, poisons and herbs, and list substances that can only be dispensed by medical doctors, pharmacists, veterinary surgeons or dentists.[206]

Health practitioners who supply therapeutic goods to their clients must do so consistently with other relevant laws. For example, in order to comply with the ACL, practitioners must avoid making misleading or deceptive claims about the therapeutic goods they supply.

Voluntary self-regulation

Self-regulation is the dominant form of regulation for most unregistered health practitioners.[207] Numerous associations, registers, federations and councils exist, which each have their own code of ethics or code of practice, regulating the activities of its members.[208] Entities such as Medicare and private health insurers generally rely on professional associations to credential unregistered health practitioners, and may require practitioners to be members of an association to be eligible to have rebates issued for their services.[209] Many health consumers also rely on practitioners' membership of a professional association as evidence that the practitioner is suitably qualified, safe to practise and subject to ethical standards.[210]

Professional bodies representing unregistered health professions vary in their regulatory approach but typically undertake the following activities:

- Setting qualification and other requirements for membership;
- Accrediting or otherwise assessing and recognising qualifying programs for membership purposes;
- Requiring members to comply with a code of ethics;
- Issuing other codes and guidance to members about good professional practice;
- Setting requirements for professional development;
- Operating a complaints process; and
- Disciplining members who are found to have breached the code of ethics or other rules of the association.[211]

There are several large and well established professional associations representing CAM professions, however, some are also fragmented (being represented by multiple bodies).[212] Examples of professional CAM associations include the Australian Register of Homeopaths,[213] the Australian Natural Therapists Association[214] and the Australian Traditional Medicine Society.[215]

Professional bodies play an important role in setting standards for members of their health profession. However, the disciplinary powers of these bodies are ultimately limited to suspension or exclusion of a person from membership of the relevant body.[216] Unlike the National Boards, professional bodies for unregistered professionals are unable to completely prohibit a person from providing a particular health service. This means that a naturopath, for example, who is excluded from an association could continue to practice as, and call themselves, a naturopath.

Negative licensing schemes for unregistered practitioners: NSW, SA and Queensland approaches

Deciding that stronger regulatory mechanisms were necessary for unregistered health practitioners, three Australian states have implemented negative licensing schemes[217], which do not restrict entry to practice (like other business or occupational licensing schemes) but allow action to be taken against practitioners who fail to comply with specified standards of conduct or practice.

NSW and SA

The NSW reforms for unregistered health practitioners came into effect on 1 August 2008.[218] The key elements of the scheme are a statutory *Code of Conduct for Unregistered Health Practitioners* (see Box J)[219] and enhanced disciplinary powers for NSW's health complaints entity, the Health Care Complaints Commission (HCCC).[220] The Code has 18 provisions (16 substantive) and numerous sub-provisions.

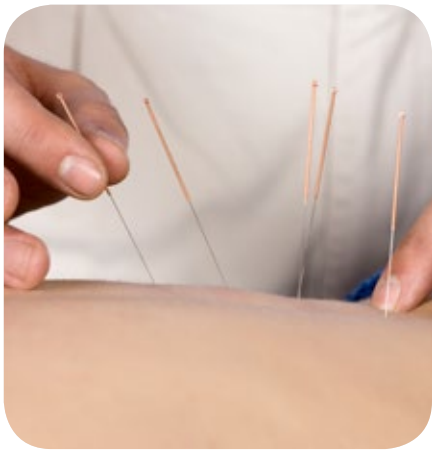
Enhanced powers for the HCCC give the Commission the power to investigate a complaint and:

- Issue a 'prohibition order' preventing a person from providing health services for a period of time;
- Issue an order placing conditions on the provision of health services; and
- Provide a warning to the public about a practitioner and his or her services.[221]

The HCCC can issue a prohibition order or public statement where:

- A provider has breached the Code of Conduct or been convicted of a 'relevant offence', and
- In the opinion of the Commission, the provider poses a risk to the health and safety of members of the public.[222]

Providing a health service in breach of a prohibition order is an offence, punishable by fines of up to $22 000 and/or 12 months imprisonment.[223]



Box J:
NSW Code of Conduct for Unregistered Health Practitioners—provisions particularly relevant to cancer patients and survivors

A practitioner:

- Must provide health services in a safe and ethical manner (for example, not providing health care of a type that is outside his or her experience or training—code 3);
- Must not make claims to be qualified, or able or willing to treat cancer and other terminal illnesses, or unsubstantiated claims about the alleviation of symptoms of those illnesses (code 5);
- Must not attempt to dissuade clients from seeking or continuing with treatment by a registered medical practitioner (code 7);
- Must not financially exploit clients (code 10);
- Must have a clinical basis for treatments and must not diagnose or treat an illness or condition without an adequate clinical basis (code 11); and
- Must not make claims about the efficacy of a treatment or service provided if those claims cannot be substantiated (code 12).

While primarily introduced to fill a gap in the regulation of unregistered practitioners, the Code also applies to registered practitioners who provide health services unrelated to the profession for which they are registered.[224]

The HCCC received approximately 90 complaints each year relating to unregistered health practitioners between 2009-12, for which it issued prohibition orders in 19 cases and two public warnings.[225] Between 2012-14 the HCCC issued a further 18 public statements and/or prohibition orders in respect of unregistered health practitioners.[226] In 2013-14 the HCCC also prosecuted a practitioner for breach of a prohibition order; the practitioner was convicted, ordered to enter into a Good Behaviour Bond for two years and was fined $12,000.[227]

SA has a negative licensing scheme which came into effect in March 2013.[228] It is almost identical to the NSW Scheme and therefore is not outlined here.

Queensland

Queensland has also introduced a negative licensing scheme which commenced on 1 July 2014.[229] The Queensland reform is broader in certain respects, creating a single body to manage health complaints against both registered and unregistered health practitioners (the former in cases of serious misconduct, taking this power from the National Boards under the National Law).[230]

The scheme provides for the establishment of a statutory Code of Conduct but this is yet to be adopted. Prohibition orders can be issued for a limited range of behaviours that are specified in the legislation, as well as any Code that may be adopted.[231]

AHMAC: proposed reforms

In light of the types of cases involving unregistered practitioners described above, as well as the move by several jurisdictions to introduce state-based schemes to regulate unregistered health practitioners, the AHMAC, commenced a review of this issue in 2010.[232] This led to a final report in 2013 (*Options for Regulation of Unregistered Health Practitioners*),[233] and a consultation paper in 2014 on a proposed negative licensing model, which would include a national Code of Conduct and powers of prohibition.[234]

AHMAC's 2013 report found that the majority of unregistered health practitioners (both CAM and others) 'practise in a safe, competent and ethical manner.'[235] However, there was evidence that a small number of individuals engage in 'exploitative, predatory and illegal behaviour' that would result in deregistration if they were members of a registered profession.[236] AHMAC also noted that such practitioners may not be members of voluntary professional associations and may even move jurisdictions to avoid the oversight of their peers.[237] Regarding cancer care, AHMAC highlighted that there were:

Numerous examples of practitioners who operate outside conventional referral and health service systems and specifically target their services directly to vulnerable cancer patients. In doing so, they may combine the use of misleading claims about their qualifications and/or treatments with pressure sales tactics, and charge unjustifiably high fees (sometimes in the tens of thousands of dollars), generally for treatments of unproven or questionable benefit. They often characterise their treatments as 'complementary or alternative medicine' (CAM) and present themselves as 'pioneers' in the treatment of patients for whom Western medicine has apparently failed. Such exploitative and predatory behaviour is not condoned by reputable CAM practitioners and brings the CAM professions into disrepute.[238]

Options for reform considered by AHMAC

The AHMAC consultation sought to determine whether there was a need for strengthened regulatory protections for consumers in states and territories without a negative licensing scheme.

Four options were considered:

1. No change to the current regulatory regime;
2. Strengthened self-regulation—i.e. introducing a voluntary code of practice and measures to improve the efficiency and effectiveness of self-regulation of the unregistered health professions;
3. Strengthened statutory health complaints mechanisms—i.e. expanding the adoption of negative licensing schemes; and
4. Extending statutory registration to all unregistered health professions.[239]

AHMAC advised against option 1, given the known deficiencies with the regulatory framework outside those states which have introduced negative licensing.[240] It also recommended against option 2 (strengthened self-regulation), given that many rogue practitioners do not actually join professional associations.[241] AHMAC further advised against option 4 (extending statutory registration to all health professions), suggesting that this was overly burdensome, costly and unnecessary in light of the low risk to the public of the services provided by many unregistered health professions.[242]

AHMAC expressed a preference for option 3—namely, strengthening health complaints mechanisms and introducing a national statutory Code of Conduct modelled on the NSW *Code of Conduct for Unregistered Health Practitioners.*[245] A national scheme could either be administered through existing state and territory health complaints entities, or a national body.[246] AHMAC suggested that the key benefits of option 3 are that it would:

- Capture all practitioners whether or not they choose to be members of self-regulating professional associations;
- Set common minimum standards of practice regardless of the profession or occupation or the nature of the practice;
- Target enforcement action to those practitioners who avoid their ethical responsibilities or who engage in predatory or exploitative behaviour towards their clients;
- Presents a relatively cost effective method of addressing the most harmful conduct and, over time, lead to an overall improvement in standards, and a better educated and informed public; and
- Provide the least cost option while being effective in achieving the objective of protecting the public and reducing harm.[247]

Possible drawbacks of this approach, however, include that it does not allow minimum qualifications to be set for health practitioners, require probity checking, or allow for protection of title usage.[248]

AHMAC proposed national reform

In response to AHMAC's 2013 report, the Standing Council on Health (SCOH), part of the Council of Australian Governments) agreed in principle in June 2013 to strengthen state and territory health complaints mechanisms by a adopting a single national Code of Conduct (to be implemented through regulation in each state and territory), as well as statutory powers to issue prohibition orders. The SCOH also agreed to a nationally accessible register of prohibition orders and mutual recognition arrangements between states and territories to support national enforcement of the Code.[249] Ministers agreed that under these proposed arrangements, each state and territory would be responsible for:

- Enacting new (or amending existing) legislation and regulations to give effect to the national Code of Conduct, the national register of prohibition orders, and mutual recognition of prohibition orders across state boundaries; and
- Determining a suitable local body to receive and investigate breaches of the Code of Conduct and issue prohibition orders.[250]

To give effect to these decisions, AHMAC was asked to undertake a public consultation on the terms of the national Code and proposed policy parameters, which would then be considered by state and territory Health Ministers.

A draft National Code of Conduct was developed through this process, based on the NSW and SA Codes. The draft has since undergone further amendments but at the time of writing, was not publicly available. It is expected that the Code will be considered by state and territory Health Ministers in the first half of 2015.

Victoria: proposed Healthcare Quality Commissioner Bill 2014

In September 2014, the Victorian Government moved to introduce a negative licensing scheme as part of a broad reform to Victoria's health complaints system. The Healthcare Quality Commissioner Bill 2014 would have replaced the OHSC and the HSCR Act. The bill was the product of two years of policy development which commenced in 2012 with the appointment of an expert panel to review the HSCR Act and modernise the Health Complaints Commissioner's approach to resolving complaints about health providers.[251]

Relevantly, the bill included powers for the renamed Healthcare Quality Commissioner to issue prohibition orders, including conditions on the provision of a service, where:

- The Commissioner reasonably believes that the health care provider has contravened a prescribed Code of Conduct; or
- The health care provider has been convicted or found guilty of a prescribed offence; and
- The Commissioner is satisfied that the order is necessary to avoid a serious risk to the life, health, safety or welfare of a person, or the health, safety or welfare of the public.[252]

The maximum penalty for an individual for non-compliance was approximately $35 500 and/or two years imprisonment (and approximately $177 000 for a body corporate).[253] Any orders made by the Commissioner would be reviewable by VCAT.[254]

The bill was introduced just prior to the November 2014 Victorian election, and has not been voted on by Parliament.

Box K:
When is a health profession suitable for registration under the NRAS?

According to the 2008 *Intergovernmental Agreement for National Registration and Accreditation Scheme for the Health Professions:*

- The sole purpose of occupational regulation is to protect the public interest; and
- The purpose of regulation is not to protect the interests of health occupations.[243]

The Agreement indicates that six questions should be answered in the affirmative before a health profession is considered for registration. These are:

1. Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry;
2. Do the activities of the occupation pose a *significant* risk of harm to the health and safety of the public? Relevant matters include the nature and severity of the risk to the client group, the wider public and to the practitioner—for example, the use of intrusive techniques or potentially dangerous substances;
3. Do existing regulatory or other mechanisms fail to address health and safety issues?
4. Is regulation possible to implement for the occupation in question? For example, is the occupation well-defined and does it possess a body of knowledge that can form the basis of standards of practice?
5. Is regulation practical to implement for the occupation in question? For example, is it likely that members of the occupation will be organised and seek compliance with regulation from their members; are there sufficient numbers of practitioners?
6. Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?[244]

[The] majority of unregistered health practitioners (both CAM and others) 'practise in a safe, competent and ethical manner.' However, there [is] evidence that a small number of individuals engage in 'exploitative, predatory and illegal behaviour' that would result in deregistration if they were members of a registered profession.

Box L:
AHMAC Draft National Code of Conduct for Health Care Workers—provisions with particular relevance to cancer patients and survivors (see full draft Code at Annex 1)

The Code applies to a 'health care worker'—both unregistered practitioners (including deregistered practitioners), and registered practitioners who provide services unrelated to their registration

1. Health care workers to provide services in a safe and ethical manner

1(2)(b) A health care worker must not provide health care of a type that is outside his or her experience or training, or provide services that he or she is not qualified to provide

1(2)(d) A health care worker must recognise the limitations of the treatment he or she can provide and refer clients to other competent health care workers in appropriate circumstances

1(2)(g) A health care worker must encourage clients to inform their treating medical practitioner (if any) of the treatments or care being provided

1(2)(h) A health care worker must have a sound understanding of any possible adverse interactions between the therapies and treatments being provided or prescribed and any other medications or treatments that a client is taking or receiving, and advise the client of these interactions

2. Health care workers to obtain [informed] consent

Prior to commencing a treatment or service, a health care worker must explain to a client the treatments or services he or she is planning to provide, including any risks involved, and obtain the consent of the client, guardian or other relevant person

3. Appropriate conduct in relation to treatment advice

3(2) A health care worker must not attempt to dissuade a client from seeking or continuing medical treatment

8. Health care workers not to make claims to cure certain serious illnesses

8(1) A health care worker must not claim or represent that he or she is qualified, able or willing to cure cancer or other life threatening or terminal illnesses

8(2) A Health care worker who claims to be able to treat or alleviate the symptoms of cancer or other life threatening or terminal illnesses must be able to substantiate such claims

9. Health care workers not to misinform their clients

9(1) A health care worker must not engage in any form of misinformation or misrepresentation in relation to the products or services he or she provides or the qualifications, training or professional affiliations he or she holds

9(2)(c) A health care worker must not make claims either directly to clients or in advertising or promotional materials about the efficacy of treatment or services he or she provides if those claims cannot be substantiated

12. Health care workers not to financially exploit clients

12(1) A health care worker must not financially exploit their clients

Discussion

This report has examined: the regulatory framework that applies to unregistered health practitioners in Victoria, including practitioners of CAM; the use of CAM by people affected by cancer; evidence regarding the effectiveness of existing regulatory mechanisms in Victoria; and options for reform. It is evident that many cancer patients choose to use CAM to support their conventional treatment, and that some use CAM in place of conventional treatments. It is therefore important that appropriate regulatory mechanisms exist to protect the public from incompetent, unethical or impaired CAM practitioners who are not registered under the National Law.

Recommendations

1. We support the negative licensing model as it appears to provide a cost-effective means of protecting the public from incompetent, unethical or impaired practitioners. We believe that a model that incorporates a national Code of Conduct, and comparable penalty provisions, would be preferable for consistency. However, if agreement among the states and territories cannot be reached, Victoria should implement a scheme with a Code of Conduct based on the draft Code of Conduct developed by AHMAC.

2. The AHMAC draft code has gone through extensive consultation and we broadly support it in its current form. However, based on consultations with our expert working group, we believe that consideration should be given to amending clause 8 to directly address the situation in which a CAM practitioner claims to be able to prolong the life of a person with cancer (or other serious illnesses), without appropriate evidence (see suggested amendment below). We recognise that this situation may be addressed by clause 9, which generally requires practitioners not to misinform clients, including about the efficacy of their treatments. However, many cancer patients undertake conventional cancer treatment in the hope of being able to prolong their life, as complete remission is not always possible. We suspect many cancer patients also visit CAM practitioners in the hope of prolonging their life and therefore it would be helpful for the Code to be explicit that claims to be able to extend a person's life must be able to be substantiated.

3. We also recommend that clause 2 be amended to be explicit that health practitioners must obtain their client's 'informed consent', not just 'consent'. This would help remind unregistered practitioners that they are subject to common law informed consent laws. To be consistent with informed consent standards that apply to the medical profession, it would also be helpful for clause 2 to be more closely modelled on the Medical Board of Australia and the NHMRC Guidelines (outlined in the informed consent section of this report)[255]. For example, the Medical Board of Australia refers to informed consent as: 'person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.'[265] Clause 2 of the AHMAC draft code only refers to explaining 'risks', not 'benefits'.

4. If Victoria adopts its own Code of Conduct that differs materially from that developed through the AHMAC process, it is important that the government engage with stakeholders on its content.

5. It is essential that the Office of the Health Services Commissioner (or a newly named body) is provided with sufficient resources to adequately administer and enforce any future Code of Conduct that may be adopted.

6. It is essential that any future negative licensing scheme is closely monitored to ensure that it meets its intended purpose and does not have any unintended negative consequences.

Suggested amendment to clause 8 of the AHMAC draft national code:

Clause 8. Health care workers not to make claims to cure certain serious illnesses

1. *A health care worker must not claim or represent that he or she is qualified, able or willing to cure cancer or other life threatening or terminal illnesses.*

2. *A health care worker who claims to be able to treat or alleviate the symptoms of cancer or other life threatening or terminal illnesses must be able to substantiate such claims.*

2A. A health care worker who claims to be able to prolong the life of a person with cancer or other life threatening or terminal illnesses must be able to substantiate such claims.

Next steps

- Working with the Victorian Government to develop and implement comprehensive reforms, including a negative licensing system

- Together with CCV's Cancer Information and Support Services, and Clinical Network, review CCV's CAM education and information materials for patients to ensure that they are clear about the extent of regulation of many CAM practitioners, and avenues for complaints if patients are unhappy with the conduct of CAM practitioners, or the treatment they have received.

About us

The McCabe Centre for Law and Cancer is a joint initiative of the Union for International Cancer Control (UICC) and CCV. Its mission is to contribute to the effective use of law for cancer prevention, treatment, supportive care and research. Working with UICC's 800+ member organisations in 155 countries, it aims to build legal capacity globally. The McCabe Centre is based at CCV in Melbourne, Australia. CCV is a global leader in cancer control, with internationally recognised expertise in areas including behavioural research and epidemiology. Within this environment, the McCabe Centre works to build connections between disciplines, creating opportunities to use the law more effectively in all aspects of cancer control.

The McCabe Centre:

- Conducts research, policy development and training
- Develops and disseminates materials on the relationship between law and cancer control
- Provides cancer control organisations and others with an interest in cancer control with a place to go for information
- Provides a forum for discussion and sharing of information and experience
- Connects lawyers, legal academics and law students with cancer control researchers and advocates and other disciplines

CCV's Strategy and Support Division includes the Cancer Information and Support Service (CISS) which provides support and evidence-based information to those affected by cancer, their families and friends; and the Clinical Network office, which supports the work of our Clinical Network (formerly the Victorian Cooperative Oncology Group or VCOG). Established in 1976, the Clinical Network consists of a state-wide representative committee, an executive committee and 16 cancer-site or task-specific advisory sub-committees, involving over 650 specialists. It is the peak multi-specialty representative oncology forum in Victoria, and its aim is to advise the Cancer Council on all clinical aspects of cancer and in particular, on research, prevention, screening, diagnosis, treatment, palliative medicine and professional education.

ANNEX - DRAFT NATIONAL CODE OF CONDUCT FOR HEALTH CARE WORKERS (AHMAC)

Definitions

Health care worker means a natural person who provides a health service.

Health service is a service defined as a health service under relevant State or Territory law for the purposes of application of this Code of Conduct.

Health complaints entity means an entity established under state or territory legislation whose functions include conciliating, investigating and resolving complaints made against health service providers and investigating failures in the health system.

Application of this Code
This Code applies to the provision of health services by:

1. Health care workers who are not subject to the scheme for registration under the *Health Practitioner Regulation National Law,* including de-registered practitioners, and
2. Health care workers who are registered health practitioners under the Health Practitioner Regulation National Law and who provide health services that are unrelated to their registration.

1. Health care workers to provide services in a safe and ethical manner

1. A health care worker must provide health services in a safe and ethical manner.
2. Without limiting subclause 1, health care workers must comply with the following:
   - a) A health care worker must maintain the necessary competence in his or her field of practice
   - b) A health care worker must not provide health care of a type that is outside his or her experience or training, or provide services that he or she is not qualified to provide
   - c) A health care worker must only prescribe treatments or appliances that serve the needs of clients
   - d) A health care worker must recognise the limitations of the treatment he or she can provide and refer clients to other competent health care workers in appropriate circumstances
   - e) A health care worker must recommend to clients that additional opinions and services be sought, where appropriate
   - f) A health care worker must assist a client to find other appropriate health care services, if required and practicable
   - g) A health care worker must encourage clients to inform their treating medical practitioner (if any) of the treatments or care being provided
   - h) A health care worker must have a sound understanding of any possible adverse interactions between the therapies and treatments being provided or prescribed and any other medications or trveatments, whether prescribed or not, that he or she is, or should be, aware that a client is taking or receiving, and advise the client of these interactions.

2. Health care workers to obtain consent

Prior to commencing a treatment or service, a health care worker must explain to a client the treatments or services he or she is planning to provide, including any risks involved, and obtain the consent of the client, guardian or other relevant person.

3. Appropriate conduct in relation to treatment advice

1. A health care worker must accept the right of his or her clients to make informed choices in relation to their health care, including the right to refuse treatment.
2. A health care worker must not attempt to dissuade a client from seeking or continuing medical treatment.
3. A health care worker must communicate and co-operate with colleagues and other health care workers and agencies in the best interests of their clients.

4. Health care workers to report concerns about the conduct of other health care workers

A health care worker who reasonably believes that another health care worker has placed or is placing clients at serious risk of harm in the course of providing treatment or care must refer the matter to [Insert name of relevant state or territory health complaints entity].

5. Health care workers to take appropriate action in response to adverse events

1. A health care worker must take appropriate and timely measures to minimise harm to clients when an adverse event occurs in the course of providing treatment or care.
2. Without limiting subclause (1), a health care worker must:
   - a) ensure that appropriate first aid is available to deal with any adverse event
   - b) obtain appropriate emergency assistance in the event of any serious adverse event
   - c) promptly disclose the adverse event to the client and take appropriate remedial steps to reduce the risk of recurrence.
   - d) report the adverse event to the relevant authority, where appropriate.

6. Health care workers to adopt standard precautions for infection control

1. A health care worker must adopt standard precautions for the control of infection in the course of providing treatment or care.
2. Without limiting subclause (1), a health care worker who carries out skin penetration or other invasive procedure must comply with the [insert reference to the relevant state or territory law] under which such procedures are regulated.

7. Health care workers diagnosed with infectious medical conditions

1. A health care worker who has been diagnosed with a medical condition that can be passed on to clients must ensure that he or she practises in a manner that does not put clients at risk.
2. Without limiting subclause (1), a health care worker who has been diagnosed with a medical condition that can be passed on to clients should take and follow advice from an appropriate medical practitioner on the necessary steps to be taken to modify his or her practice to avoid the possibility of transmitting that condition to clients.

8. Health care workers not to make claims to cure certain serious illnesses

1. A health care worker must not claim or represent that he or she is qualified, able or willing to cure cancer or other life threatening or terminal illnesses.
2. A health care worker who claims to be able to treat or alleviate the symptoms of cancer or other life threatening or terminal illnesses must be able to substantiate such claims.

9. Health care workers not to misinform their clients

1. A health care worker must not engage in any form of misinformation or misrepresentation in relation to the products or services he or she provides or the qualifications, training or professional affiliations he or she holds.
2. Without limiting subclause (1):
   - a. A health care worker must not use his or her possession of a particular qualification to mislead or deceive clients or the public as to his or her competence in a field of practice or ability to provide treatment
   - b. A health care worker must provide truthful information as to his or her qualifications, training or professional affiliations
   - c. A health care worker must not make claims either directly to clients or in advertising or promotional materials about the efficacy of treatment or services he or she provides if those claims cannot be substantiated.

10. Health care workers not to practise under the influence of alcohol or drugs

1. A health care worker must not provide treatment or care to clients while under the influence of alcohol or unlawful drugs.
2. A health care worker who is taking prescribed medication must obtain advice from the prescribing health practitioner or dispensing pharmacist on the impact of the medication on his or her ability to practise and must refrain from treating or caring for clients in circumstances where his or her capacity is or may be impaired.

11. Health care workers with certain mental or physical impairment

1. A health care worker must not provide treatment or care to clients while suffering from a physical or mental impairment, disability, condition or disorder (including an addiction to alcohol or a drug, whether or not prescribed) that places or is likely to place clients at risk of harm.
2. Without limiting subclause (1), if a health care worker has a mental or physical impairment that could place clients at risk, the health care worker must seek advice from a suitably qualified health practitioner to determine whether, and in what ways, he or she should modify his or her practice, including stopping practice if necessary.

12. Health care workers not to financially exploit clients

1. A health care worker must not financially exploit their clients.
2. Without limiting subclause (1):
   - a) a health care worker must only provide services or treatments to clients that are designed to maintain or improve clients' health or wellbeing
   - b) a health care worker must not accept or offer financial inducements or gifts as a part of client referral arrangements with other health care workers
   - c) a health care worker must not accept financial inducements or gifts from the suppliers of medicines or other therapeutic goods or devices
   - d) a health care worker must not ask clients to give, lend or bequeath money or gifts that will benefit the health care worker directly or indirectly

13. Health care workers not to engage in sexual misconduct

1. A health care worker must not engage in behaviour of a sexual or close personal nature with a client.
2. A health care worker must not engage in a sexual or other close personal, physical or emotional relationship with a client.
3. Before engaging in a sexual or other close personal, physical or emotional relationship with a former client, a health care worker should ensure that a reasonable period of time has elapsed since the conclusion of the therapeutic relationship.

14. Health care workers to comply with relevant privacy laws

A health care worker must comply with the relevant privacy laws that apply to clients' health information, including the Privacy Act 1988 (Cth) and the [insert name of relevant state or territory legislation]

15. Health care workers to keep appropriate records

1. A health care worker must maintain accurate, legible and up-to-date clinical records for each client consultation and ensure that these are held securely and not subject to unauthorised access.
2. A health care worker must take necessary steps to facilitate clients' access to information contained in their health records if requested.
3. A health care worker must facilitate the transfer of a client's health record in a timely manner when requested to do so by the client or their legal representative.

16. Health care workers to be covered by appropriate insurance

A health care worker must ensure that appropriate indemnity insurance arrangements are in place in relation to his or her practice.

17. Health care workers to display code and other information

1. A health care worker must display a copy of each of the following documents at all premises where the health care worker carries on his or her practice:
   a. a copy of this Code of Conduct
   b. any relevant qualifications that the health care worker possesses
   c. a document that gives information about the way in which clients may make a complaint to [insert name of state or territory health complaints entity].
2. Copies of those documents must be displayed in a position and manner that makes them easily visible to clients entering the relevant premises.
3. This clause does not apply to any of the following premises:
   a. the premises of any entity within the public health system (as defined in the [insert name of relevant state or territory legislation])
   b. private health facilities (as defined in [insert name of relevant state or territory legislation])
   c. premises of the [insert name of ambulance service] as defined in ([insert name of relevant state or territory legislation])
   d. premises of approved aged care service providers (within the meaning of the Aged Care Act 1997 (Cth)).

References

1 See for example, Kerry Haynes, Kate Scalzo and Victoria White, *The PROSPECT Program Patient Responses: An Ongoing Survey of People Experiencing Cancer Treatment* (Cancer Council Victoria, 2014, unpublished); Breast Cancer Network Australia, *Submission to the Senate Community Affairs References Committee Inquiry into Out-of-pocket costs in Australian healthcare* (2014) 10; Cancer Voices Australia, *Submission to the Senate Community Affairs References Committee Inquiry into Out-of-pocket costs in Australian healthcare* (2014); Maxine Morand, 'The Advocacy Perspective: The Financial Cost to Women of Breast Cancer Treatment and Care' (Presentation to the World Cancer Congress, Melbourne, 4 December 2014); and Breast Cancer Network Australia, *The Support and Information Needs of Women with Secondary Breast Cancer 2014: Report 1 (Financial Issues)* (2014).

2 Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (2014), and National Health and Medical Research Council (NHMRC), *General Guidelines for Medical Practitioners on Providing Information to Patients* (2004) and NHRMC, *Communicating with Patients: Advice for Medical Practitioners* (2004).

3 Vicki Thursfield et al, *Cancer in Victoria: Statistics and Trends 2013* (Cancer Council Victoria, 2014) 9.

4 Ibid.

5 Ibid.

6 Ibid 12.

7 See McCabe Centre for Law and Cancer, *Making the Law Work Better for People Affected by Cancer: 2013 Report* (Cancer Council Victoria, 2014).

8 Cancer Council Victoria's Clinical Network (formerly the Victorian Cooperative Oncology Group) is a peak multi-specialty representative oncology forum in Victoria, comprising more than 600 health professionals, which aims to promote a range of cooperative measures to optimise cancer management in Victoria.

9 *Medical Treatment Act 1988* (Vic) ss 5, 5A.

10 Victorian Parliament Law Reform Committee, Inquiry into powers of attorney Parliamentary Paper No 352 (2010) xv

11 Victorian Law Reform Commission, *Guardianship Final Report* Final Report 24 (2012) 126.

12 Ibid 142.

13 Robert Clark MP, Attorney General, Minister for Finance, Minister for Industrial Relations (Vic) 'Clearer and simpler guardianship and administration laws' (Media release, 20 August 2014) < http://www.robertclark.com.au/news/attorney-general/clearer-and-simpler-guardianship-and-administration-laws/>

14 Ibid.

15 Ibid.

16 The Law Institute of Victoria's submission to the Victorian Attorney General on the proposed amendments to the Guardianship and Administration Bill 2014 highlights concerns with the inconsistency between the new definition in clause 4 (and the POA Act) and a separate test for decision-making capacity for medical treatment in clause 142 of the bill. The LIV submitted that different tests may lead to confusion for health professionals giving effect to guardianship laws. The delayed passage of the Bill may allow for further consideration of how these sections operate together. See Law Institute of Victoria, Submission to the Victorian Attorney General, *Proposed Amendments to the Guardianship and Administration Bill 2014*, 7 October 2014, 9.

17 Medical Board of Australia, above n 2, code 3.5.

18 *Secretary of Department of Health & Community Services v JWB* (Marion's Case) (1992) 175 CLR 218, 265-268 (Brennan J). See generally Loane Skene, *Law and Medical Practice: Rights, Duties, Claims and Defences* (LexisNexis Butterworths, 3rd ed, 2008) 81-84.

19 V Dharmananda, to the Law Reform Commission of Western Australia, *Informed Consent to Medical Treatment: Processes, Practices and Beliefs* Law Reform Commission of Western Australia, December 1992, 9-10.

20 Senate Community Affairs References Committee, *Out-of-pocket costs in Australian healthcare* (2014) 64.

21 Andrew J Gogos et al, 'When Informed Consent Goes Poorly: A Descriptive Study of Medical Negligence Claims and Patient Complaints' (2011) 195(6) *Medical Journal of Australia* 340, 340. Further, of medical negligence claims made against doctors in Victoria, NSW and Queensland, about 3.4 per cent included complaints about informed consent.

22 Ibid 340, 342.

23 Haynes, Scalzo and White, above n 1, 17.

24 Ibid.

25 Michael Jefford and Martin H N Tattersall, 'Informing and Involving Cancer Patients in Their Own Care' (2002) 3 *The Lancet: Oncology* 629, 629-636. See also, e.g., Ian N Olver et al, 'Impact of an Information and Consent Form on Patients Having Chemotherapy' (1995) 162 *Medical Journal of Australia* 82.

26 Ibid, 631, citing W J Mackillop et al, 'Cancer patients' perceptions of their disease and its treatment' (1988) 58(3) *British Journal of Cancer* 355.

27 Senate Community Affairs References Committee, above n 20, 64. See also Productivity Commission, *Public and Private Hospitals: Productivity Commission Research Report* (December 2009); Ipsos, *Consumer Survey – Informed Financial Consent* (Prepared for Australian Government, Department Of Health and Ageing, 2007). These studies concerned IFC for all types of health care consumers.

28 Haynes, Scalzo and White, above n 1, 45.

29 Ibid 45-46.

30 See, for example, Breast Cancer Network Australia, above n1, and Cancer Voices Australia, above n 1.

31 See, for example, Morand, above n 1. This study reported that women with secondary

breast cancer in Australia have average monthly out-of-pocket expenses of $687. See further Breast Cancer Network Australia, *The Support and Information Needs of Women with Secondary Breast Cancer 2014*, above n 1.

[32] Consumers Health Forum of Australia, 'Informed Financial Consent Discussion Paper' (November 2012) 7 <https://www.chf.org.au/pdfs/rep/rep-971-Informed-financial-consent-discussion-paper.pdf>.

[33] Note that this report will use the term medical practitioners interchangeably with doctors, to describe medical doctors (and not other providers, for example, osteopaths, who may also call themselves doctors).

[34] Contract law and consumer law are also relevant. Common law is law made by the courts, as opposed to legislation which is enacted by parliament.

[35] *Rogers v Whitaker* (1992) 175 CLR 479, 483 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).

[36] Ibid.

[37] The common law position has been affirmed in legislation in Victoria, which makes it clear that health practitioners satisfy their duty of care to provide warnings of risk and other information, if they take reasonable care in doing so (s 50, *Wrongs Act 1958* (Vic)).

[38] *Rogers v Whitaker* (1992) 175 CLR 479, 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ). Emphasis added.

[39] Skene, above n 18, 45, 190.

[40] *Rogers v Whitaker* (1992) 175 CLR 479, 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ). See R S Lord, 'Informed Consent in Australia' (1995) 65 *Australian New Zealand Journal of Surgery* 224, 224.

[41] *Rogers v Whitaker* (1992) 175 CLR 479, 489 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ); *Rosenberg v Perival* (2001) 205 CLR 434; 439; *Wrongs Act 1958* (Vic) s 60. See Janine McIlwraith and Bill Madden, *Health Care and the Law* (Thomson Reuters, 6th ed, 2014) 274-75.

[42] See Skene, above n 18, 210; McIlwraith and Madden, above n 40, 291; *Chatterton v Gerson* [1981] 1 QB 432, 443 (Bristol J).

[43] See Skene, above n 18, 210-11.

[44] Richard Cavell, 'Towards a Better Consent Form' (2007) 14 *Journal of Law and Medicine* 326, 328. See also Azim Nagree, 'Consent Forms and the Medical Profession' (1997) 4 *Journal of Law and Medicine* 336, 337-341.

[45] See Skene, above n 18, 211.

[46] A failure to mention fees does not appear to have been the subject of an action for negligent non-disclosure: see Skene, above n 18, 191.

[47] Cost may be considered a 'material' factor, per *Rogers v Whitaker*, for most patients, especially where there is a choice between different treatment options. It has previously been suggested that doctors have a duty to inform patients of "any available alternatives" (*Rosenberg v Percival* (2001) 205 CLR 434 at 465 para 101; 178 ALR 577, per Kirby J), although not to the point of being burdensome (*Richards v Rahilly* (2005) NSWSC 352 at [234]-[237]). These cases, however, all refer to the risk of harm arising from treatment so as to maximize bodily integrity, rather than concerns over cost.

[48] *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013* (Vic) reg 20.

[49] Medical Board of Australia, above n 2.

[50] Unprofessional conduct is a lesser standard of behaviour than that which is reasonably expected by the public or the practitioner's professional peers: *Health Practitioner Regulation National Law Act* sch ss 5, 196(1)(b). The National Law was established in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld) and then enacted by other states including Victoria: *Health Practitioner Regulation National Law (Victoria) Act 2009*.

[51] Professional misconduct involves more serious forms of unprofessional conduct: see *Health Practitioner Regulation National Law Act* sch ss 5, 196(1)(b).

[52] *Health Practitioner Regulation National Law Act* sch s 196(2).

[53] [2006] VCAT 1920 (25 August 2006).

[54] Medical Board of Australia, above n 2, code 3.5.

[55] NHMRC, *General Guidelines*, above n 2. Originally adopted in 1993, these were re-endorsed in 2004. The NHMRC is Australia's peak body for, among other things, providing advice on ethical behaviour in health care. The *General Guidelines* were developed in 1993 in response to the recommendations of a joint inquiry by the Victorian, New South Wales and Australian Law Reform Commissions: see Law Reform Commission of Victoria, Australian Law Reform Commission and New South Wales Law Reform Commission, *Informed Decisions about Medical Procedures* (1989).

[56] NHMRC, *Communicating with Patients*, above n 2. These were developed in 2004, recognising that how doctors communicate with patients, not just what they communicate, is important.

[57] Ibid 7-8.

[58] Medical Board of Australia, above n 2, codes 3.5.3, 3.5.4

[59] See, e.g., Australian Medical Association, *Code of Ethics* (2004, revised 2006); Royal Australasian College of Surgeons, *Informed Consent Policy* (2006).

[60] Australian Medical Association, *Informed Financial Consent – 2006* (2006) <https://ama.com.au/node/5091>.

[61] NHMRC, *General Guidelines*, above n 2, 7-12.

[62] Ibid.

[63] Australian Medical Association, above n 2.

[64] See Department of Human Services, *Medicare Services* (14 January 2015) <http://www.humanservices.gov.au/customer/subjects/medicare-services>; Private Health Insurance Ombudsman, *What is Covered by Medicare* <http://www.privatehealth.gov.au/healthinsurance/whatiscovered/medicare.htm>.

[65] See Iselect, *What is the Medical Gap Scheme* <http://www.iselect.com.au/private-health-insurance/info/hospital-cover/medical-gap.jsp>; Department of Human Services, above n 64; Private Health Insurance Ombudsman, above n 64.

[66] Breast Cancer Network Australia, *Submission to the Senate Community Affairs References Committee Inquiry*, above n 1, 4.

[67] Productivity Commission, above n 27, 209.

[68] Senate Community Affairs References Committee, above n 20. These figures are for 2012-13.

[69] Breast Cancer Network Australia, *Submission to the Senate Community Affairs References Committee Inquiry,* above n 1, 5.

[70] Ibid 7.

[71] Cancer Council, *Understanding Clinical Trials and Research: A Guide for People Affected by Cancer* (2012) 54; Consumers Health Forum of Australia, 'Consumer Guide to Clinical Trials' (2013) 3.

[72] Department of Human Services, above n 64; Private Health Insurance Ombudsman, above n 64.

[73] Ibid.

[74] Senate Community Affairs References Committee, above n 20, 14.

[75] Department of Human Services, above n 64; Private Health Insurance Ombudsman, above n 64.

[76] For example, acupuncture attracts a Medicare rebate if performed by a medical doctor and osteopathy attracts a Medicare rebate if provided under a GP Management Plan: Department of Health, *Chronic Disease Management - Individual Allied Health Services under Medicare - Patient Information* (20 February 2014) <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-medicare-allied-health-brochure.htm>.

[77] Department of Human Services, above n 64.

[78] Department of Human Services, *Benefits of a Health Care Card* (25 September 2014) <http://www.humanservices.gov.au/customer/enablers/centrelink/health-care-card/benefits>.

[79] Senate Community Affairs References Committee, above n 20, 46.

[80] Consumers Health Forum of Australia, 'Informed Consent in Healthcare: An Issues Paper' (March 2013) 6.

[81] Ibid.

[82] See, e.g., Ian N Olver et al, 'Improving Informed Consent to Chemotherapy: A Randomised Control Trial of Written Information Versus an Interactive Multimedia CD-ROM' (2009) 74 *Patient Education and Counselling* 198, 202, 203; Jefford and Tattersall, above n 25, 629, at 630, citing P Maguire and A. Faulkner 'Communicate with cancer patients: 1 Handling bad news and difficult questions' (1988) 297 *British Medical Journal* 907.

[83] See Ian N Olver et al, 'Improving Informed Consent to Chemotherapy', above n 82; Jefford and Tattersall, above n 25; and G C Barnett, 'Information Given to Patients about Adverse Effects of Radiotherapy: A Survey of Patients' Views' (2004) 16 *Clinical Oncology* 479, 481.

[84] See NHMRC, *Communicating with Patients*, above n 2, 4, 8, 12-13.

[85] Loane Skene and Richard Smallwood, 'Informed consent: lessons from Australia' (2002) 324 *British Medical Journal* 39; Seham Tawfick Girgis, Colin Thomson and Jeanette Ward, 'The Courts Expect the Impossible: Medico-legal Issues as Perceived by NSW General Practitioners' (2000) 7 *Journal of Law and Medicine* 273, 280.

[86] Consumers Health Forum of Australia, 'Informed Consent', above n 80, 7.

[87] Ibid.

[88] Cavell, above n 44, 330.

[89] See Jefford and Tattersall, above n 25, 633-35.

[90] See Ian N Olver, Anne E Taylor and Hayley S Whitford, 'Relationships between Patients' Pre-Treatment Expectations of Toxicities and Post Chemotherapy Experiences' (2005) 14 *Psycho-Oncology* 25, 28; Sophie Lewis, Karen Willis and Marika Franklin, 'Don't Panic! Healthy Consumers Look Online for Medical Advice', *The Conversation* (12 February 2014) <http://theconversation.com/dont-panic-healthy-consumers-look-online-for-medical-advice-20951>.

[91] See Angela Coulter, Vikki Entwistle and David Gilbert, 'Sharing Decisions with Patients: Is the Information Good Enough?' (1999) 318 *British Medical Journal* 318, 318.

[92] See Olver et al, 'Impact of an Information and Consent Form on Patients Having Chemotherapy', above n 25, 82. See also Michael Jefford and Rosemary Moore, 'Improvement of Informed Consent and the Quality of Consent Documents' (2008) 9 *Lancet: Oncology* 485, 486.

[93] See Cancer Council, above n 71, 43-45; Emma Beardsley, Michael Jefford and Linda Mileshkin, 'Longer Consent Forms for Clinical Trials Compromise Patient Understanding: So Why are they Lengthening?' (2007) 25 *Journal of Clinical Oncology* 13, 13. Clinical trials are used to test new ways of preventing, diagnosing and treating diseases, including cancer.

[94] Olver et al, 'Impact of an Information and Consent Form on Patients Having Chemotherapy', above n 25; Consumers Health Forum of Australia, 'Informed Consent', above n 80, 6, citing M.M. Bottrell et al., 'Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient Physician Interaction' (2000) 135(1) *Archives of Surgery* 26, 33.

[95] Jeffrey P. Spike, 'Common ethical problems in acute care surgery', in Laura J. Moore, Krista L. Turner, and S. Rob Todd (eds.), *Common Problems in Acute Care Surgery* (Springer, New York, 2013) 487, 493.

[96] See Productivity Commission, above n 27, 211-12; Consumers Health Forum of Australia, 'Informed Financial Consent', above n 32, 10-13.

[97] See Senate Community Affairs References Committee, above n 20, 63.

[98] NJ Meropol, D Schrag, TJ Smith et al, 'American Society of Clinical Oncology Guidance Statement: the Cost of Cancer Care' (2009) 27 *Journal of Clinical Oncology* 3868; D Schrag, M Hanger, 'Medical oncologists' views on communicating with patients about chemotherapy costs: A pilot survey' (2007) 25 *Journal Clinical Oncology* 233; PJ Neumann et al, 'Cancer therapy costs influence treatment: A national survey of oncologists' (2010) 29 *Health Affairs (Millwood)* 196.

[99] The focus groups were of two hours duration. A small financial gratuity was provided for attendance.

[100] Ninety-three of 104 respondents strongly agreed or agreed that they received enough relevant information from their doctors about their cancer diagnosis and 92 of 104 that they understood the information provided. Fifty per cent of survey respondents received the most information about their diagnosis from their surgeons. The next largest categories were medical oncologists (37 per cent) and radiation oncologists (six per cent).

[101] Eight respondents answered that they were 'unsure'.

[102] Eight respondents were unsure.

[103] Five respondents were unsure.

[104] Four respondents were unsure.

[105] Fourteen persons were unsure.

[106] Respondents also received treatments such as targeted therapies (including antibodies and immune treatments) and anti-cancer drugs like Tamoxifen.

[107] Ninety-two of 104 respondents strongly agreed or agreed that they received enough relevant information from their doctors about their cancer treatment and 93 of 103 that they understood it. The majority of survey respondents (54 per cent) received the most information about their treatment from their medical oncologists. The next largest categories were surgeons (36 per cent) and GPs (five per cent).

[108] Ninety of 102 respondents strongly agreed or agreed that they received the information they needed from their doctors to make an informed decision about their treatment.

[109] Eight respondents were unsure and 4 preferred not to understand.

[110] Thirteen respondents received a DVD or video. One respondent's doctor used a decision aid

and two respondents were given an audio recording of their consultation.

[111] Five respondents were unsure.

[112] Nine respondents were unsure.

[113] Fifteen respondents were unsure.

[114] Seven respondents were unsure.

[115] Six respondents were unsure.

[116] Nine respondents were unsure.

[117] Six respondents were unsure.

[118] Twelve respondents were unsure.

[119] Six respondents were unsure.

[120] Two respondents were unsure.

[121] Nine respondents were unsure.

[122] The respondent stated that the radiologist was going to start treatment without providing this information and only discussed it once it was raised by the patient.

[123] Five respondents were unsure.

[124] One respondent was unsure.

[125] Eighteen were unsure.

[126] Five respondents were unsure.

[127] Sixteen respondents strongly agreed, and 46 agreed, that they received enough information.

[128] Eight respondents were unsure.

[129] Nine respondents were unsure.

[130] Six respondents were unsure.

[131] Six respondents were unsure.

[132] Five respondents were unsure.

[133] Twenty-two respondents were unsure.

[134] Consumers Health Forum, 'Informed Financial Consent', above n 32, 7.

[135] See for example, Haynes, Scalzo and White, above n 1, 45; Breast Cancer Network Australia, *Submission to the Senate Community Affairs References Committee Inquiry*, above n 1, 10; Cancer Voices Australia, above n 1; Morand, above n 1; and Breast Cancer Network Australia, *The Support and Information Needs of Women with Secondary Breast Cancer 2014*, above n 1.

[136] Senate Community Affairs References Committee, above n 20, 64.

[137] Ibid.

[138] Cancer Council Australia, *Position Statement: Complementary and Alternative Therapies* (2013) (16 January 2015) <http://wiki.cancer.org.au>.

[139] Also known as mainstream, medical or orthodox treatments: Ibid; National Center for Complementary and Alternative Medicine, *Complementary, Alternative, or Integrative Health: What's In a Name?* (July 2014) <http://nccam.nih.gov/health/whatiscam/>.

[140] Also known as holistic, natural or traditional therapies, or traditional medicine.

[141] Also known as unconventional treatment: Cancer Council Australia, above n 138.

[142] Cancer Council Australia, above n 138. For recent studies examining the use of CAM in Australia see, e.g.: R Walshe et al, 'Socio-demographic and Medical Correlates of the use of Biologically Based Complementary and Alternative Medicines amongst recent Australian Cancer Survivors' (2012) 54 *Preventive Medicine* 23; J Gillett et al, 'Complementary and Alternative Medicine use in Radiotherapy: What are Patients Using?' (2012) 18 *Journal of Alternative and Complementary Medicine* 1014; Byeongsang Oh et al, 'The Use and Perceived Benefits Resulting from the Use of Complementary and Alternative Medicine by Cancer Patients in Australia' (2010) 6 *Asia-Pacific Journal of Clinical Oncology* 342; T Kremser et al, 'Use of Complementary Therapies by Australian Women with Breast Cancer' (2008) 17 *Breast* 387; C Pirri et al 'Use of Complementary and Alternative Therapies by Western Australian Cancer Patients' (2008) 4 *Asia Pacific Journal of Clinical Oncology* 161; C Xue et al, 'Complementary and Alternative Medicine use in Australia: A National Population-based Survey' (2007) 13 J*ournal of Alternative and Complementary Medicine* 643; M Markovic et al, 'Complementary Medicine use by Australian Women with Gynaecological Cancer' (2006) 15 *Psychooncology* 209; and A MacLennan, S Myers, A Taylor, 'The Continuing use of Complementary and Alternative Medicine in South Australia: Costs and Beliefs in 2004' (2006) 184 *Medical Journal of Australia* 27.

[143] See Cancer Council Australia, above n 138.

[144] Ibid.

[145] Ibid.

[146] Cancer Council Australia, above n 138. See also Cancer Council Victoria, *Complementary Therapies* (29 June 2012) <http://www.cancervic.org.au/about-cancer/types-treatments-trials/about_alternative_treatments>.

[147] See N Klafke et al, 'Prevalence and Predictors of Complementary and Alternative Medicine (CAM) use by Men in Australian Cancer Outpatient Services' (2012) 23 *Annals of Oncology* 1571. See also Cancer Council Victoria, above n 146.

[148] Cancer Council Victoria, *Complementary therapies: Key Questions* (29 June 2012) <http://www.cancervic.org.au/about-cancer/types-treatments-trials/about_alternative_treatments/key-questions.html>.

[149] See Klafke, above n 147, 1573.

[150] See Julia Medew, 'Complementary 'Medicines' may Cause Harm During Cancer Treatment', *The Age* (online), 3 December 2014 <http://www.theage.com.au/national/health/complementary-medicines-may-cause-harm-during-cancer-treatment-20141202-11yn7s.html>.

[151] Ibid.

[152] Cancer Council Australia, above n 138.

[153] Ibid.

[154] Cancer Council Victoria, *Complementary and Alternative Medicine: Making Informed Decisions* (Fact Sheet, 2012) 2.

[155] Cancer Council Australia, above n 138.

[156] Ibid.

[157] Clinical Oncology Society of Australia, *Position Statement: The Use of Complementary and Alternative Medicine by Cancer Patients* (May 2013) 6-7. Emphasis added. See also Lesley Braun et al, 'Clinical Oncology Society of Australia Position Statement on the Use of Complementary and Alternative Medicine by Cancer Patients' (2014) *Asia-Pacific Journal of Clinical Oncology* 1.

[158] Due to constitutional limitations on the federal government, the National Law was established through co-operation with the States and Territories. The National Law was adopted in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld) and then enacted in other jurisdictions including Victoria: *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic).

[159] In Victoria, the *Health Professions Registration Act 2005* (Vic)

[160] *Health Practitioner Regulation National Law Act 2009* sch s 31.

[161] *Health Practitioner Regulation National Law Act 2009* sch ss 5, 35(1)(a)-(c), 55(a)(b)(h), 112.

[162] A lesser standard of behaviour than that which is reasonably expected by the public or the practitioner's professional peers: *Health Practitioner Regulation National Law Act 2009* sch s 5.

[163] Means the knowledge, skill or judgment possessed, or care exercised by, the practitioner is below the standard reasonably expected of a health practitioner of an equivalent level of training or experience in that registered profession: *Health Practitioner Regulation National Law Act*: ibid.

[164] Includes: (a) unprofessional conduct by the practitioner that amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and (b) more than one instance of unprofessional conduct that, when considered together, amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and (c) conduct of the practitioner, whether occurring in connection with the practice of the health practitioner's profession or not, that is inconsistent with the practitioner being a fit and proper person to hold registration in the profession: ibid.

[165] Means the person has a physical or mental impairment, disability, condition or disorder (including substance abuse or dependence) that detrimentally affects or is likely to detrimentally affect (a) the person's capacity to practise the profession; or (b) for a student, the student's capacity to undertake clinical training: ibid.

[166] Ibid sch s 193.

[167] Ibid sch s 196(2)(b)(d)(e). Note that when less serious matters are referred to a National Board or Panel conditions can also be placed on the person's practise by the relevant body: s 178, 191.

[168] Ibid sch section 196(4)(a)(b).

[169] See Australian Health Ministers' Advisory Council (AHMAC), *Review of the National Registration and Accreditation Scheme for Health Professions* (Consultation Paper, 2014) 12.

[170] For an example of a case under the National Law involving a registered medical practitioner and a cancer patient, see *Fluhrer, Dr Joachim* [2013] NSWMPSC 7 (29 July 2013). For an example of a case against a registered medical practitioner under legislation preceding the National Law, see for example: *Medical Board of Australian and Boyd* [2013] WASAT 123. Boyd, a Perth doctor, was involved in the treatment of seriously ill cancer patients with various alternative substances, including some not approved for medical treatment purposes, or subject to strict limitations (caesium, DMSO – an industrial solvent – and laetrile). The treatment was carried out, mainly by two nurses, at Dr Boyd's home and she received a substantial payment for her involvement. The Tribunal found that the Board's allegations of misconduct were established and removed Dr Boyd's name from the register of medical practitioners. For broader background on this case, see: Coroner's Report, *Inquest into the deaths of Sandra McCarty, Pia Bosso, Sandra Kokalis, Deborah Gruber & Carmelo Vinciullo* (2012).

[171] [2012] VCAT 1614.

[172] Formally the *Competition and Consumer Act 2010* (Cth) sch 2. Implemented in Victoria by the *Australian Consumer Law and Fair Trading Act 2012* (Vic). Commencing in 2011, the Competition and Consumer Act replaced the *Trade Practices Act 1974* (Cth).

[173] *Competition and Consumer Act 2010* (Cth) sch 2 ss 18, 21, 23, 29, 33, 34.

[174] The *Australian Consumer Law and Fair Trading Act 2012* (Vic) specifies that the ACL is a law of Victoria and sets out CAV's functions and authorities. The ACL is applied as a law of the Commonwealth; each state and territory has made the provisions of the ACL a law of its jurisdiction so that the same laws apply across Australia and can be enforced by all courts and tribunals, including the courts and tribunals of the states and territories: Fitzroy Legal Service Inc, 'Consumer Protection Legislation' (30 June 2013) <http://www.lawhandbook.org.au/handbook/ch12s03.php>. A co-operation agreement between ACCC and Consumer Affairs Victoria exists in order to provide each agency with mutual assistance in relation to the exchange of information, appropriate referral of matters, and cooperation in compliance education and enforcement activities: Consumer Affairs Victoria, *Our role, scope and policies* (2015) (see <http://www.consumer.vic.gov.au/about-us/who-we-are-and-what-we-do/our-role-scope-and-policies/conciliation-policy>).

[175] See Australian Competition and Consumer Commission, *Competition and Enforcement Policy* <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>.

[176] *Australian Consumer Law and Fair Trading Act 2012* (Vic) ss 109, 110, 113, 114, 115.

[177] *Competition and Consumer Act 2010* (Cth) sch 2 s 223; *Australian Consumer Law and Fair Trading Act 2012* (Vic) s 228.

[178] *Competition and Consumer Act 2010* (Cth) sch 2 s 232; *Australian Consumer Law and Fair Trading Act 2012* (Vic) s 201.

[179] *Competition and Consumer Act 2010* (Cth) sch 2 s 219.

[180] Ibid sch 2 Part 5-2, divs 3 and 4.

[181] See generally e.g. Michael Weir et al, 'Complementary and Alternative Medicine and Consumer Law' (2013) 21 *Competition and Consumer Law Journal* 85; Ian Freckelton, 'Unscientific Health Practice in Disciplinary and Consumer Protection Litigation' (2011) 18 *Journal of Law and Medicine* 645.

[182] [2011] VSC 153; [2012] VSCA 91.

[183] Health Services Commissioner, *Noel Campbell Inquiry Report* (2008) 102.

[184] (2012) VCAT Reference : C6583/2011

[185] Ibid. 4

[186] [2007] NSWSC 1130.

[187] [2007] FCA 695.

[188] (No 5) [2011] FCA 49.

[189] AHMAC, *Options for Regulation of Unregistered Health Practitioners: Final Report* (2013) 14.

[190] See Office of the Health Services Commissioner (28 January 2015) <http://www.health.vic.gov.au/hsc/>.

[191] *Health Services (Conciliation & Review) Act 1987* (Vic) ss 3(1), 16. Pursuant to s 3(1) "health service" includes medical, hospital and nursing services; dental services; psychiatric services; pharmaceutical services; ambulance services; community health services; health education services; welfare and social work services necessary to implement any of the aforementioned services; therapeutic counselling and psychotherapeutic services; laundry, cleaning and catering services, where those services affect health care or treatment of a person using or receiving a service referred to in this definition; services provided by chiropodists, chiropractors, osteopaths, dietitians, optometrists, audiologists, audiometrists, prosthetists, physiotherapists and psychologists; services provided by optical dispensers, masseurs, occupational therapists and speech therapists; services provided by practitioners of naturopathy, acupuncture and in other alternative health care fields; services provided by Chinese herbal medicine practitioners, acupuncturists and Chinese herbal dispensers; a service prescribed as a health service for the purposes of the Act; and any service provided by the Department of Health

and the Secretary to the Department of Health.

[192] Ibid ss 19, 20. Appropriate matters involving registered health practitioners are referred to the relevant National Board: s 19(6).

[193] Office of the Health Services Commissioner, *Annual Report* (2014) 26, 43.

[194] See Office of the Health Services Commissioner, *Information for Complainants* (15 December 2014) <http://www.health.vic.gov.au/hsc/resources/infosheet.htm>.

[195] *Health Practitioner Regulation National Law Act 2009* sch ss 113, 116.

[196] Ibid.

[197] Ibid s 123.

[198] *Rogers v Whitaker* (1992) 175 CLR 479, 483 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ). See earlier discussion of negligence law.

[199] See Janine McIlwraith and Bill Madden, *Health Care and the Law* (5h ed, Lawbook Co, 2010) 201-202. See, for example, *Bawden v Marin* [1990] SASC (2 July 1990) (chiropractor found to have acted negligently); *Wrongs Act 1958* (Vic) s 58.

[200] See e.g., *Wrongs Act 1958* (Vic) s 48; *Rogers v Whitaker* (1992) 175 CLR 479. See earlier discussion of informed consent.

[201] See, e.g., Michael Weir, Law and Ethics in Complementary Medicine (Allen & Unwin, 4th ed, 2010) 140; McIlwraith and Madden (2010), above n 41, 328.

[202] Some states also have legislation either implementing or complementing the CTGA: in Victoria the *Therapeutic Goods (Victoria) Act 1994* (Vic).

[203] Therapeutic Goods Administration, *Medicines and TGA Classifications* Department of Health, (28 October 2014) <http://www.tga.gov.au/industry/regulation-basics-medicines-classifications.htm#.VC4drcvlruQ>.

[204] Ibid.

[205] Generally criminal and civil penalties apply if a person has not obtained a licence to manufacture therapeutic goods for use in humans in Australia: *Commonwealth Therapeutic Goods Act 1989* (Cth) ss 35, 35A. However, exemptions exist under schedule 7 and schedule 8 for herbalists, nutritionists, naturopaths, traditional Chinese medicine practitioners and homoeopathic practitioners who make preparations for the purpose of treating their patients.

[206] In Victoria, the relevant act is the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

[207] See AHMAC, *Final Report*, above n 189, 17-18.

[208] Weir, above n 201, 19.

[209] See AHMAC, *Final Report*, above n 189, 5, 19-24.

[210] Ibid 17-18.

[211] Ibid 17.

[212] See AHMAC, *Final Report*, above n 189, 18.

[213] Australian Register of Homoeopaths, <www.aroh.com.au>.

[214] Australian Natural Therapists Association, <http://www.australiannaturaltherapistsassociation.com.au>.

[215] Australian Traditional Medicine Society <http://www.atms.com.au>.

[216] Weir, above n 189, 19, 21-55.

[217] This followed government various government reviews, see, for example: New South Wales Parliament, Joint Committee on the Health Care Complaints Commission, *Review of the 1998 Report into Unregistered Health Practitioners: The Adequacy and Appropriateness of Current Mechanisms for Resolving Complaints* (2006); Parliament of South Australia, Social Development Committee, *Inquiry into Bogus, Unregistered and Deregistered Health Practitioners* (2009).

[218] Minor amendments have been made since first introduced: see Health Care Complaints Commission (NSW), *Information for Unregistered Health Practitioners* (12 February 2014) <http://www.hccc.nsw.gov.au/Information/Information-for-unregistered-practitioners/Default>.

[219] Made under the *Public Health Act 2010* (NSW) s 100. Originally made under the *Public Health Act 1991* (NSW). The Code is set out in Schedule 3 *Public Health Regulation 2012* (NSW). The Code was originally called the *Code of Conduct for Unregistered Practitioners 2008*. See Ian Freckelton, 'Legal Implications for CAM Practitioners of the NSW Health Practitioner Code of Conduct' (2013) 20 *Journal of Law and Medicine* 734, 735.

[220] As established by the *Health Care Complaints Act 1993* (NSW).

[221] See, e.g., *Health Care Complaints Act 1993* (NSW) s 41A; AHMAC, above n 189, 24; Health Care Complaints Commission (NSW), above n 218.

[222] *Health Care Complaints Act 1993* (NSW) s 41A. A relevant offence is an offence under pt 7 *Public Health Act 2010* (NSW), the *Fair Trading Act 1987* (NSW) or the *Competition and Consumer Act 2010* (Cth) that relates to the provision of health care services.

[223] *Public Health Act 2010* (NSW) s 102.

[224] *NSW Code of Conduct for Unregistered Health Practitioners*, code 2.

[225] See AHMAC, *Final Report,* above n 189, 27.

[226] NSW Health Care Complaints Commission, 'Annual Report 2013-14' (Annual Report, 2014) 43.

[227] Ibid.

[228] SA Health, *Unregistered Health Practitioners: Code of Conduct* (2014) Government of South Australia.

[229] *Health Ombudsman Act 2013* (Qld).

[230] The Health Ombudsman can issue interim orders against a practitioner: ibid pt 7, div 2. The Queensland Civil and Administrative Tribunal (QCAT) can issue final orders: pt 10, div 4. The Act provides that the Health Ombudsman or QCAT, in deciding whether to issue an interim prohibition or final prohibition, respectively, must consider whether the practitioner poses a serious risk to persons whether because of the practitioner's health, performance or conduct: ss 68, 113.

[231] Actions specified by the Act, which can result in a prohibition order being issued, include: practising the practitioner's profession unsafely, incompetently or while intoxicated by alcohol or drugs; financially exploiting a person; engaging in a sexual or improper personal relationship with a person; discouraging a person from seeking clinically accepted care or treatment; making false or misleading claims about the health benefits of a particular health service, or making false or misleading claims about the practitioner's qualifications, training, competence or professional affiliations: see ss 68(2), 113(2).

[232] AHMAC, *Options for Regulation of Unregistered Health Practitioners: Consultation Paper* (2011) 1. For another high profile instance of an unregistered CAM practitioner providing unsuitable treatment to a cancer patients, see, e.g., State Coroner, *Inquest into the Death of Penelope Dingle* (Western Australia, Ref 17/10, 2010).

[233] AHMAC, *Final Report,* above n 189.

[234] AHMAC, *A National Code of Conduct for Health Care Workers (Consultation Paper)* (2014).

[235] AHMAC, *Final Report*, above n 189, 5.

[236] Ibid.

[237] Ibid.

[238] Ibid. 32-33.

[239] Ibid 6-7.

[240] Ibid 53.

[241] Ibid 55-56.

[242] Ibid 58.

[243] Commonwealth of Australia et al, *Intergovernmental Agreement for National Registration and Accreditation Scheme for the Health Professions* (2008) 23.

[244] Ibid.

[245] AHMAC, *Final Report*, above n 189.

[246] Ibid.

[247] Ibid 83.

[248] Ibid 47.

[249] See AHMAC, *A National Code of Conduct,* above n 234.

[250] Ibid 6.

[251] See Expert Review Panel, 'Final Report on the Review of the Health Services (Conciliation and Review) Act 1987' (Department of Health (Vic), January 2013).

[252] Healthcare Quality Commissioner Bill 2014 cls 96- 97, 101-02.

[253] Ibid cls 103.

[254] Ibid cls 106.

[255] Medical Board of Australia, above n 2, and NHMRC, *General Guidelines and Communicating with Patients*, above n 2.

[256] Medical Board of Australia, above n 2, code 3.5.

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