HOLMAN WEBB LAWYERS

Health Law Bulletin

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Introduction

Welcome to the September 2016 edition of the Holman Webb Health Law Bulletin.

"Without continual growth and progress, such words as improvement, achievement, and success have no meaning": Benjamin Franklin

The theme of this Health Law Bulletin is "Improving Patient Outcomes".

With an increasing aging population and decreasing financial resources, innovation is essential in improving health care delivery and patient outcomes.

How can we use innovative solutions to deliver "improved" health "outcomes" rather than "outputs" or "activity"?

How can we use clinical governance to improve patient outcomes?

In terms of clinical governance, we can learn from other countries and industries, such as the aviation industry which is also highly regulated and responsible for the safety of numerous people.

"But one of the challenges for the airline piloting profession is to avoid complacency, to always be prepared for whatever may come while never knowing when or even if you'll face an ultimate challenge…It's so important for people to find jobs suited to their strengths and their passions. People who love their jobs work more diligently at them. They become more adept at the intricacies of their duties. They serve the world well…I flew thousands of flights in the last forty-two years, but my entire career is now being judged by how I performed on one of them. This is a reminder to me: We need to try to do the right thing every time, to perform at our best, because we never know which moment in our lives we'll be judged on." [1]

Captain Chesley "Sully" Sullenberger

The same applies for clinical governance, medical adverse events and investigations.

This Health Law Bulletin discusses the latest developments in outcomes based contracting in health care, lessons learnt in relation to clinical governance arising from recent Government Inquiries, as well as recent developments in consumer directed care.

We trust that this edition of the Health Law Bulletin brings to you articles of relevance to the sector.

The health, aged care/retirement living and life science sectors form an important part of the Australian economy. They are economic growth areas, as more Australians retire with a significantly longer life expectancy and complex health care needs.

Against this background, Holman Webb's health, aged care and life sciences team provides advice that keeps pace with the latest developments. Our team has acted for health and aged care clients over a number of years, both in the "for profit" and the "not for profit" sector.

Some of our team members have held senior positions within the health industry.

Please do not hesitate to contact me or any member of our legal team should you have any questions about the Health Law Bulletin content and articles or if one of your colleagues would like to be added to our distribution list. ■

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[1] "*Highest Duty, My Search for What Really Matters*, Captain Chesley "Sully" Sullenberger pages 107 and 113, Harper.

Clinical Governance Update - Review of Serious Failures in Reported Test Results for Prostate Specific Antigen (PSA) Testing of Patients by SA Pathology; Bankstown-Lidcombe Hospital Medical Gas Findings Report

By Alison Choy Flannigan, Partner

Clinical governance is the term used to describe a systematic approach to maintaining and improving the quality of patient care within a clinical care setting, health program or health system. It is about the ability to produce effective change so that high quality care is achieved. It requires clinicians and administrators to take joint responsibility for making sure this occurs.[2]

Australia has an excellent health care system, one of the best in the world. However, no health care system is perfect and on occasion, adverse events occur and errors are made. We have a positive obligation to prevent them from occurring. Clinical governance is the system tool which should act as a "safety-net" in order to prevent adverse events occurring and to effect change such that improvements can be made.

There have been two recent reports which have touched on the issue of clinical governance:

This article discusses each case briefly and draws out the clinical governance lessons for health and aged care providers, so that they may learn from these experiences to improve future patient outcomes.

1. Review of Serious Failures in Reported Test Results or PSA

The Australian Commission on Safety and Quality in Health Care published its report titled *"Review of Serious Failures in Reported Test Results for Prostate-specific Antigen (PSA) Testing of Patients by SA Pathology"* in July 2016. The Report is discussed below.

1.1 Facts

(a) From March 2015, SA Pathology began reporting levels of Prostate-specific Aantigen (**PSA**) in patients at low levels following requests from urologists who found the results useful in monitoring their patients who had their prostates removed – as men without a prostate gland should have no detectable PSA. The presence of PSA, even at low levels, may indicate the need for further treatment.

(b) From 7 November 2015 the assay lots used by SA Pathology to detect PSA were inaccurate between the ranges of 0.03 – 0.08 micrograms per litre (ug/L) with a positive bias of 0.03 ug/L. Consequently, the PSA results for patients reported from this date, within this range, showed detectable PSA levels where PSA was undetectable, and higher levels of PSA where there were low detectable levels. From 17 March 2016 SA Pathology reported tests on two different methods simultaneously.

(c) The report states that SA Pathology failed to act on the inaccurate PSA results despite technical warnings generated by their laboratory systems. One potential warning was inadvertently switched off and another was noted without its potential to detect the error being realised.

(d) SA Pathology did not become aware of the inaccurate results it was producing until a complaint from a urologist at the end of January 2016. The complaint was wrongly classified with a low level of severity and, although SA Pathology did take the appropriate action to determine the cause of the inaccurate readings, that action was slow and not consistent with the urgency of the situation.

(e) Complaints continued to be made to SA Pathology about PSA results through February and March 2016. SA Pathology determined to discontinue the defective test from six months after dual reporting was introduced. Until then, SA Pathology continued to report the inaccurate results to clinicians. On 18 March 2016, SA Pathology wrote to all urologists explaining the problem with the test and the move to a new test, and placed a notice on the SA Pathology website. The public notice was framed as a routine notice without sufficient explanation to be considered as adequate notification to the public.

(f) The report found that SA Pathology's complaint handling, open disclosure, governance and accountability systems during this period was totally inadequate.

(g) Following media exposure of the issue in early April 2016, significant and appropriate action was taken by SA Pathology. A "lookback" process was commenced to identify the number of patients affected by the inaccurate tests.

(h) The review found the management structure of SA Pathology did not provide for sufficient clinical supervision of, and accountability for, laboratory process. The review was briefed regarding a separate management review of SA Pathology which considered SA Pathology's structure dysfunctional and different from contemporary management structures in place in pathology laboratories throughout Australia.

(i) The review's expert chemical pathologist analysed data from SA Pathology and determined that the test kits in question were inaccurate at levels of 0.03 – 0.08 ug/L. As these kits were distributed to a number of laboratories in Australia, the review has provided its expert advice to the manufacturer and the Therapeutic Goods Administration.

[2] Definition derived from the Clinical Governance web page on the NSW Ministry of Health website (www.health.nsw.gov.au)

1.2. **Summary of Major Findings**

The review made the following findings:

(a) SA Pathology's internal quality assurance processes were inadequate. SA Pathology failed to act on technical warnings from the laboratory system that the tests were inaccurate in low level PSA test results from assay kits in use from 7 November 2015. No action was taken until a complaint from a urologist in late January 2016.

(b) The complaint was not given the appropriate level of attention and SA Pathology's investigations were slow. When SA Pathology did finally determine that the problem resulted from the test kits it was using, its action to notify affected users was totally inadequate and failed to appreciate the anxiety and distress of the inaccurate results on those patients who received the results.

(c) When the issue received public attention, appropriate action was, and has since been taken, to identify the patients affected and notify their treating clinicians.

(d) Management, governance and accountability at SA Pathology was seriously deficient. The review agrees with the findings and proposals of a separate management review recommended a restructure to bring SA Pathology in line with management practices in place at comparable Australian providers.

1.3. **Clinical Governance Lessons**

(a) The review found that SA Pathology failed to properly monitor and respond to the alerts from its automated testing.

(b) Whilst concern was mounting among urologists and their patients who were calling SA Pathology to express theirt concern, these calls were not formally treated as complaints as they should have been, and consequently there were no entries in Q-Pulse and the Safety Learning System.

(c) The classification of the first complaint with a severity assessment code of 4 was inconsistent with the serious nature of the issue and the potential number of patients affected. The low classification also had the result that more senior staff in both SA Pathology and SA Health were not notified and did not have the opportunity to consider how it should be managed.

(d) The clinical significance of the inaccurate low level PSA readings was not appreciated and action to investigate the cause was not pursued with any sense of urgency.

(e) The severity of the problem was underrated resulting in no senior level notification and investigation as required by policies. There was no attempt to identify affected patients and no attempt to develop a comprehensive plan to notify them despite the knowledge that the inaccurate tests result could lead to misdiagnosis and unnecessary treatment.

(f) During the review it became apparent that the structure of the organisation did not provide sufficient clinical input and management accountability at appropriate levels, and quality assurance procedures were not sufficient to identify emerging issues and problems and ensure appropriate management.

(g) The review included a recommendation to engage an appropriately qualified and experienced person to implement an organisation structure for SA Pathology that:

(i) aligns appropriately skilled staff placement with the operational needs of the service;

(ii) provides adequate clinical expertise to monitor and inform the production of results;

(iii) clearly defines the responsibilities and accountabilities of staff; and

(iv) ensures the requirements of referring clinicians are reflected in the work rules of the service.

2. Bankstown-Lidcombe Hospital Medical Gas Findings Report

2.1 Facts

(a) The NSW Chief Health Officer's Final Report into the Bankstown-Lidcombe Hospital medical gas incident was released on 27 August 2016 and found a series of tragic errors led to the failed resuscitation of two babies.

(b) One of the babies died and the other has been left with serious health issues.

(c) Dr Kerry Chant's report was provided to the families of the two babies on Friday morning, 26 August.

(d) The two babies were born at Bankstown-Lidcombe Hospital earlier this year – one in June and the other in July. Both babies needed resuscitation after birth.

2.2 Major Findings

(a) Dr Chant's report found that mislabelling of existing gas pipes resulting in incorrect installation of additional medical gas pipes in one of the Bankstown-Lidcombe Hospital's operating theatres, which was not picked up during installation or by the testing and commissioning of the pipes, led to the two babies being resuscitated with nitrous oxide instead of oxygen. The process of testing for gas purity is the ultimate test to ensure that the right gas comes out of the right outlets.

2.3 Clinical Governance Lessons

(a) The report also found broader clinical and corporate governance issues at the Hospital, specifically around the project planning and risk management of the commissioning of clinical infrastructure.

(b) A recommendation was to review senior management's role in the broader governance (both clinical and corporate) of the commissioning of clinical infrastructure at the hospitals.

3. Commentary and Summary of Clinical Governance Lessons Learnt

There are some common clinical governance themes which run through these two cases, including as follows:

(a) In each case, there was an indicator that there was an issue, however, for one reason or another, the issue was not escalated appropriately to senior management. Health care providers must ensure that there is adequate ability for staff to notify their concerns to senior management, through a number of alterative avenues and staff should be trained on severity indicators.

(b) Involving a multi-disciplinary team is important because the team provides peer review and a check and balance.

(c) It is really important to check that what you are doing is in accordance with a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice. This was an issue in both cases.

(d) In one of the cases disharmony in culture appears to be a contributing factor.

(e) In one of the cases, for various reasons, there was a delay in dealing with the issue once it was raised to senior management. If there is a significant issue, then the matter needs to be escalated and dealt with urgently by senior management.

(f) Adverse event reporting, investigation, root cause analysis, look back, open disclosure and communication and media policies should be in place and followed.

(g) In both cases, management accountability is raised.

(h) In both cases, the use of technology, such as software, could have been used to identify the issue.

Social impact investing/ outcome-based contracts in health – opportunities and challenges

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

With an increasing aging population and decreasing financial resources, innovation is essential in improving health care delivery and patient outcomes.

Better Outcomes for People with Chronic and Complex Health Conditions

In December 2015, the Commonwealth Department of Health published the report of the Primary Health Care Advisory Group (**Advisory Group**) titled "*Better Outcomes for People with Chronic and Complex Health Conditions*". [3]

The report states that our current primary health care system works well for the majority of Australians. However, for the growing number of people with chronic and complex conditions, care can be fragmented and the system can be difficult to navigate.

Through consultations with patients, carers, doctors, allied health professionals and health system organisations the Advisory Group identified a model of care supported by a new way of funding that can transform the way we provide primary health care for Australians with chronic and complex conditions.

Central to the reform is the establishment of Health Care Homes, which provide continuity of care, coordinated services and a team based approach according to the needs and wishes of the patient.

This new approach is supported by new payment mechanisms to better target available resources to improve patient outcomes.

The new approach offers an opportunity to improve and modernise primary health care and maximise the role of patients as partners in their care. It represents innovative, evidence-based best practice that harnesses the opportunity of digital health care. Importantly, it has strong support from consumers and health care professionals alike.

Central to the proposed reform is the formalisation of the relationship between the patient with chronic and complex conditions and their Health Care Home: a setting where they can receive enhanced access to holistic coordinated care, and wrap around support for multiple health needs.

Health Care Home

Key features of the Health Care Home are:

- **Voluntary patient enrolment** with a practice or health care provider to provide a clinical 'home-base' for the coordination, management and ongoing support for their care.
- **Patients, families and their carers as partners in their care** where patients are activated to maximise their knowledge, skills and confidence to manage their health, aided by technology and with the support of a health care team.
- **Patients have enhanced access** to care provided by their Health Care Home in-hours, which may include support by telephone, email or videoconferencing and effective access to after-hours advice or care.
- **Patients nominate a preferred clinician** who is aware of their problems, priorities and wishes, and is responsible for their care coordination.
- **Flexible service delivery and team based care** that supports integrated patient care across the continuum of the health system through shared information and care planning.
- **A commitment to care which is of high quality and is safe.** Care planning and clinical decisions are guided by evidence-based patient health care pathways, appropriate to the patient's needs.
- **Data collection and sharing** by patients and their health care teams to measure patient health outcomes and improve performance.

One of the recommendations was in relation to restructuring the payment system to support the new approach, including testing new payment methods to Australian Primary Health Networks (**PHNs**) to enable them to commission appropriate non-general practice clinical care and coordination services for enrolled patients in their region based on the patient's allocated risk stratification level, prior to wider rollout.

Australian Primary Health Networks Commissioning Projects

Since the release of the report, the PHNs have been tasked to adopt a commissioning approach to procuring medical and health care services. *The PHN Commissioning - Needs Assessment Guide*[4] has been developed by the Department of Health to support PHNs in planning and undertaking a needs assessment process that will identify and analyse health and service needs within their regions and prioritise activity to address those needs.

The guide provides an overview of the PHN commissioning framework and discusses the key elements of needs assessment, including the steps involved in conducting health needs analysis and service needs analysis, synthesising the evidence and determining priorities and options.

[3] http://www.health.gov.au/internet/main/publishing.nsf/Content/76B2BDC12AE54540CA257F72001102B9/$File/Primary-Health-Care-Advisory-Group_Final-Report.pdf

[4] The Needs Assessment Guide is available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/PHN-Needs_Assessment_Guide

Social Impact Investment in New South Wales

The NSW Government is backing two social benefit bonds, also known as social impact bonds.

The first bond is funding UnitingCare Burnside's New Parent and Infant Network (**Newpin**) program[5], which is working to restore children in foster care with their families and preventing at-risk children from entering care by educating parents about family environments.

The second bond, which was launched by the Benevolent Society, also relates to foster care.[6]

NSW Government has commissioned the Office of Social Impact Investment: http://www.osii.nsw.gov.au/ and has published a Social Impact Investment Policy and various materials.

Types of outcomes based contracting

Outcomes based contracting is contracting on a basis where Governments financially reward service providers or private investors for having a positive and sustained impact on the lives of service users.[7] There are four main categories of outcome funding models namely:

(a) Payment for performance, which sees a portion or sometimes all of the contractual payments conditional on achieving outcomes based targets;

(b) Social impact bonds, whereby private capital is used to fund interventions aimed at solving complex social problems. Dividends are paid if sponsored interventions deliver measured improvements;

(c) Performance based contracting, which sees a change to procurement processes of Government based upon the track record of service for the organisations achieving specified outcomes; and

(d) Performance incentive funding, whereby service providers are awarded bonus payments for achieving improvements in client outcomes.[8]

[5] https://www.facs.nsw.gov.au/about_us/media_releases/australias-first-social-benefit-bond-continues-to-deliver-for-families
[6] https://benevolent.org.au/about/social--benefit--bonds

[7] Gold and Mendelsohn, *Better Outcomes for Public Services, Achieving Social Impact Through Outcomes Based Funding*, Mowat Centre, August 2014
[8] Ibid, page 15.

Opportunities

Some of the first outcomes based models came from prisoner parole reoffending programs (the UK Peterborough Prison program is considered the model of a successful program based upon payment for performance). The success of these programs on a contractual basis maybe linked to the fact that the target populations were easily identified, namely offenders released on parole. In these programs there is also quality data available to measure performance.

The benefit for Government is that government doesn't need to determine how the services will be delivered and sets such out in a contract, but rather leaves it open to the service providers to innovate utilising their knowledge of service delivery to the target population, and are doing so pursuant to a contract which incentivises them to achieve special outcomes.

There are many areas in which quite clear outcomes may be achieved and measured against cash savings. For example, a program could be measured of savings in the pharmaceutical benefits scheme funding for the reduction in unnecessary prescriptions of a specified therapeutic good. Any such program could be funded by a percentage of savings and if successful the service provider should be able to profit from the results.

In fact, in the delivery of human and social services there must be a place in all contracting arrangements whereby an outcome connected with a service recipient's experience could become a contractual measure.

Of course, these areas should see a driving focus on outcomes as justification for the funding restraints currently experienced by all such Government organisations. The model addresses issues such as being able to justify spending in a complex area where the costs saving may only have a distant connection with the costs of funding the project. What immediately springs to mind, of course, is mental health whereby a project aimed at early intervention could be measured from (by way of example) a reduction in homelessness or welfare benefits measures.

Challenges

There are a number of challenges with outcomes based contracting in health care, these include:

- establishing the health needs requirements;
- defining the target population and stakeholders – it is easier to define and measure outcomes with respect to a smaller and more clearly defined population, such as the clients of one particular service of one provider, as compared to State/Territory or National based populations;
- establishing a contracting framework in which there will be a "win – win" for the parties;
- because health care is provided by a multi-disciplinary team, we need to be able to break down the silos in terms of contractual responsibility. Traditionally lawyers seek to clearly define each party's responsibilities and liabilities based upon the fact that a breach will cause a right of damages or termination. In outcomes based contracting, this will continue for certain obligations. However, the distinction is that a return will be paid for an outcomes based result or saving (the "win-win"). Therefore, the model is not to punish for non-performance, but to reward for performance;
- patient safety and outcomes is paramount, so the model must have checks and balances to ensure that patient safety is not compromised. Therefore, in health care, there will ultimately be a "blend" of minimum key performance indicators and outcomes based contracting overlayed; and
- being able to define and measure the benchmark and the outcomes based result – to an extent this is limited by the availability of "clean", reliable and "objective" (rather than "subjective") and continually collected health data so that the outcome can be appropriately measured.

The collection of health data is relevant to the recent debate concerning the benefit of collecting population statistics by the census versus privacy rights.

Improving patient outcomes for our Aboriginal and Torres Strait Islander Community

By Nathan Taylor, Aboriginal Health Worker, St Vincent's Health Network

My name is Nathan Taylor, I am Tubba-Gah man from the Wiradjuri Nation. I am also the Aboriginal Health Worker at St Vincent's Health Network, Sydney. Given my role as an Aboriginal Health Worker, I will predominately be providing my answers from a health perspective.

The modern history of Australia since colonisation has led to the Aboriginal and Torres Strait Islander Peoples having a difficult relationship with the various institutions that exist within our society e.g. 'health, justice, education'. In today's society, a higher proportion of Aboriginal and Torres Strait Islander Peoples have a lower socioeconomic status, when compared to the general population, meaning they have poorer health, poorer education, and higher rates of incarcerations, among other factors. All these factors cumulatively contribute to the life-expectancy of an individual, which is why the significance of 'closing the gap' in life-expectancy between the Aboriginal and Torres Strait Islander Peoples, and the general population, has become so important.

To properly improve outcomes for our Aboriginal and Torres Strait Islander communities we need to properly address not just the social determinants, but also the cultural needs of the individuals, the families, and the communities. However, due to effects of colonisation, and the various government policies since then, it has become increasingly difficult in today's society to separate the cultural needs of our Aboriginal and Torres Strait Islander Peoples, from the needs of those living within low socioeconomic conditions. The two are often talked about interchangeably, to a point where disadvantage has become synonymous with the various Aboriginal and Torres Strait Islander cultures.

In answering the below questions I will try to make the separation clearer, and only address the cultural needs of a patient.

1. ***In meeting with an Aboriginal and/or Torres Strait Islander whose English communication skills are limited, what methods could be used to better communicate, including in obtaining a medical history, family history and life style? What questions should be and should not be asked?***

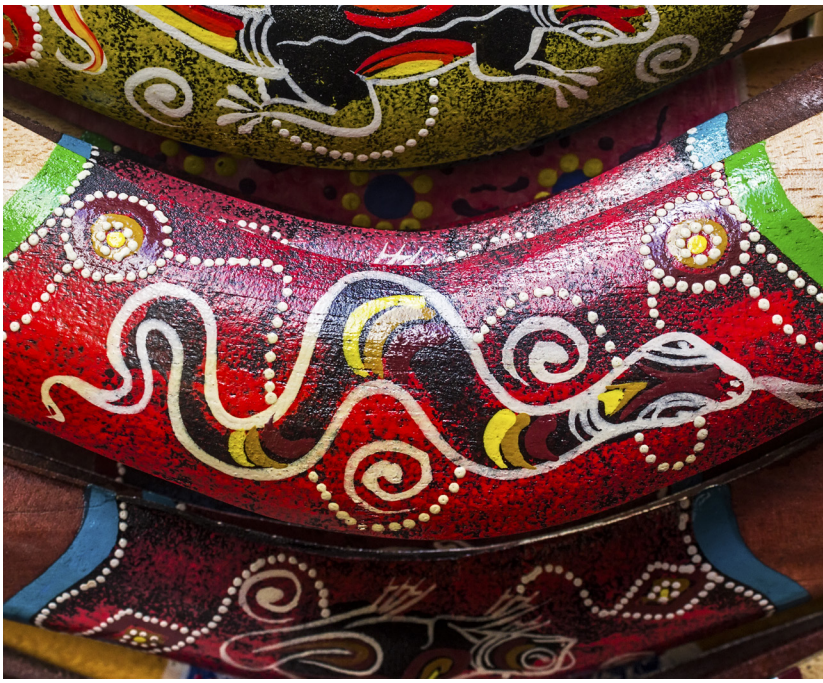
Health, or the idea of health, can often be interpreted differently amongst patients from different Nations, communities, and even families, so there is no one-size-fits-all method to approaching this.

In my role I have found that patients identify with, and convey their health in holistic terms that relate more to their social and emotional wellbeing, rather than their physical wellbeing. Factors that are important to social and emotional wellbeing include a person's connection to country, spirituality and ancestry, relationships with family members and friends, and connection to community. However, it would be wrong to exclude the fact that poor health literacy within some individuals exists, with the association of a cause and effect, such as alcohol abuse and liver damage, not always known or understood properly.

In order to obtain the relevant information to perform your role, the health discussion should take a less formal approach through asking questions about an individual's family, and community and showing genuine empathy by validating or acknowledging how a patient might be feeling emotionally about their health. This can be an effective way of developing a good rapport with the patient.

2. ***Are there any special issues to be considered in obtaining consent to medical treatment?***

For a practitioner or clinician, it may be a relatively minor health procedure or treatment option, but it can be a daunting prospect for a patient. For this reason, individuals may wish to have family involved in the conversations surrounding major health considerations, and it would be best to ask the patient if they would prefer their family, and/or the Aboriginal Health Worker to be present when seeking consent for surgery or medical treatment.



3. ***Can you please explain the role of community members and Elders? In dealing with Elders, how should they be addressed? What is their authority?***

Within my Nation, the Wiradjuri Nation, the Elders are the keepers of knowledge, and oversee the education of the youth, the upholding of cultural beliefs and protocols, and seasonal migration to ensure sustainable use of the land. In today's society, the Elders roles still encompass many of the same values, but have also taken on roles that encompass our modern society such as community activism, and the representing the communities in dealing with corporations and governments.

Elders are currently addressed or known by the titles of Uncle, for males, and Aunty, for females. This is not a title that is formally bestowed, but rather signifies the status and respect an individual has within a community. The Elders within the Wiradjuri Nation are represented by the Wiradjuri Council of Elders; similar representative bodies exist within other Nations.

4. ***Can you please explain men's and women's business? Is it best to have a doctor/nurse of the same gender involved?***

Traditionally, these terms were used to represent how knowledge and cultural protocols were taught, and shared. In the Wiradjuri Nation, information was taught by the male Elders to the male youth; with the female Elders teaching the female youth.

In a modern health context, this would mean having a male Nurse/Doctor treating someone of the same gender, however in practice this is not always an available option. Some health Institutions have male and female Aboriginal Health Workers, others do not. I myself am a male Aboriginal Health Worker, and approx. 50% of my patients are female. Even as an Aboriginal person, I will ask in my first interaction if the patient would feel more comfortable speaking with a female Social Worker. These considerations of, and observing cultural protocols, can be significant in making a patient more receptive and comfortable in a delicate situation.

5. ***What about communicating future appointments and medications?***

As well as communicating the significance of future appointments and medications, it is important to address any inhibiting factors that could limit whether or not an individual might be able to attend an appointment, despite agreeing to it. When communicating future appointment and medications, ask questions that can address hindrances e.g. 'Do you have a way to get to the hospital? Do you have family who can bring you to your appointment? Do you know where the local pharmacy is, or have a preferred one? Have you used a Webster pack before? If I need to contact you, what is the best way to do so?'

In addressing the inhibiting factors, it will give the patient greater power and responsibility over their health care, and give you the opportunity to further build an open, honest, and positive relationship with your patient.

6. ***Are there holistic medicine issues to be considered?***

See question 1.

7. ***What interpreter services are available?***

Language revitalisation, particularly in South-Eastern Australia, is still in its infancy; I am not aware of any interpretation services that currently exist. Where the languages of Nations are still spoken more frequently, such as Northern and North-Western Australia, there may be interpretation services available. In other parts of the country, it would be best to involve your Aboriginal Health Worker, Aboriginal Liaison Officer, or other institution equivalent, when engaging with patient/client.

8. ***What can and cannot be said about death and the deceased or other issues?***

The protocols surrounding death vary from Nation to Nation. For instance, within the various cultures of the Noongar Peoples of WA, the first name of the recently deceased in not said for a period of time until the community sees fit; these protocols are, however, not shared across the country. To find out more information relevant to your community, you can seek advice and understanding from your local Elders Group/Council, Aboriginal Incorporated Body such as the Aboriginal Medical Services and Aboriginal Community Controlled Health Organisations, and Aboriginal Land Council.

9. ***What is taboo?***

Again, in a broader sense, to find out more specific information about the Nation's culture that your city is located in, you should seek advice from the local Elders Group/Council, Aboriginal Incorporated Body such as the Aboriginal Medical Services and Aboriginal Community Controlled Health Organisations, and Aboriginal Land Council. This can also vary in individuals, and it is important to be mindful of institutional, and/or intergenerational trauma, this is when an Aboriginal Mental Health Worker or other appropriate mental health services should be engaged.

Whilst not taboo, something that is often done, in order to build report with a patient, is to relay that you have been to or worked in an Aboriginal Community elsewhere in Australia. While that fact is in and of itself fantastic, it is not always relevant to the patient, and may come off as disingenuous. The similarities between the cultures, and communities in Arnhem Land in Northern Australia and the Biripi Nation on the Eastern Seaboard, are vastly different. It is better to ask the patient about where they are from, as their community and Nation will hold more significance.

10. ***How else can patient outcomes for our Indigenous and Torres Strait Islander Community be improved?***

As I hope this has come through in my answers, empowering our individuals to take further control and ownership over their health is an important way to improve patient outcomes within our communities. Aboriginal Community Controlled Health Services are also an effective means for improving health outcomes. ■

Consumer Directed Care Update and brokerage arrangements

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

What is consumer directed care?

The requirement to provide home care packages on a consumer directed care basis (**CDC**) commenced on 1 July 2015.

The *Home Care Packages Operations Manual*[9] states (at page 14) that the *User Rights Principles 2014* and the *Charter of care recipients' rights and responsibilities-homecare* (the **Charter**), which recognise the rights and responsibilities of consumers and providers, explicitly acknowledge the key elements of CDC, emphasising the right of consumers to exercise choices in relation to the care provided to them.

Choice and flexibility

The Charter specifies consumers' right to:

- be supported by the provider to set goals, determine the level of ongoing involvement that they wish to have, and make decisions relating to their own care and to maintain their independence as far as possible;
- choose the care and services that best meet their goals, preferences and assessed needs, within the limits of the resources available;
- have choice and flexibility in the way the care and services are provided at home;
- participate in making decisions that affect them; and
- have their representative participate in decisions relating to their care.

Care and services

Consumers have the right to:

- receive care and services which are appropriate to meeting their goals, preferences and assessed needs;
- be given a written plan of the care and services that they expect to receive;
- receive care and services that take into account their preferences; and
- ongoing review of the care and services they receive, as required.

The User Rights Principles sets out the rights and responsibilities in relation to home care.

Care Recipient Rights

Each care recipient has the following rights:

General

(a) to be treated and accepted as an individual, and to have his or her individual preferences respected;

(b) to be treated with dignity, with his or her privacy respected;

(c) to receive care that is respectful of him or her, and his or her family and home;

(d) to receive care without being obliged to feel grateful to those providing the care;

(e) to full and effective use of all human, legal and consumer rights, including the right to freedom of speech regarding his or her care;

(f) to have access to advocates and other avenues of redress;

(g) to be treated without exploitation, abuse, discrimination, harassment or neglect;

Consumer directed care—choice and flexibility

(a) to be supported by the Approved Provider:

(i) to set goals in relation to the outcomes he or she seeks from home care;

(ii) to determine the level of ongoing involvement and control that he or she wishes to have in the provision of the home care;

(iii) to make decisions relating to his or her own care; and

(iv) to maintain his or her independence as far as possible;

(b) to choose the care and services that best meet his or her goals and assessed needs and preferences, within the limits of the resources available;

(c) to have choice and flexibility in the way the care and services are provided at home;

(d) to participate in making decisions that affect him or her;

(e) to have his or her representative participate in decisions relating to his or her care if he or she requests it or if he or she does not have capacity;

[9] https://agedcare.health.gov.au/ageing-and-aged-care-programs-services/home-care-packages-operational-manual

Consumer directed care—care and services

(a) to receive reliable, coordinated, safe, quality care and services which are appropriate to meeting his or her goals and assessed needs;

(b) to be given before, or within 14 days after, he or she commences receiving home care, a written plan of the care and services that he or she expects to receive;

(c) to receive care and services that take account of his or her other care arrangements and preferences;

(d) to ongoing review of the care and services he or she receives (both periodic and in response to changes in his or her personal circumstances), and modification of the care and services as required;

Individualised budget and monthly statement of available funds and expenditure

(a) to receive an individualised budget for the care and services to be provided;

(b) to have his or her individualised budget reviewed and, if necessary, revised if:

(i) the care and services to be provided, or the costs of providing the care and services, change; or

(ii) he or she requests the approved provider to review and, if necessary, revise the individualised budget;

(c) to receive a monthly statement of the funds available and the expenditure in respect of the care and services provided during the month;

Personal information

(a) to privacy and confidentiality of his or her personal information;

(b) to access his or her personal information;

Communication

(a) to be helped to understand any information he or she is given;

(b) to be given a copy of the Charter;

(c) to be offered a written agreement that includes all agreed matters;

(d) to choose a person to speak on his or her behalf for any purpose;

Comments and complaints

(a) to be given information on how to make comments and complaints about the care and services he or she receives;

(b) to complain about the care and services he or she receives, without fear of losing the care or being disadvantaged in any other way;

(c) to have complaints investigated fairly and confidentially, and to have appropriate steps taken to resolve issues of concern;

Fees

(a) to have his or her fees determined in a way that is transparent, accessible and fair;

(b) to receive invoices that are clear and in a format that is understandable;

(c) to have his or her fees reviewed periodically and on request when there are changes to his or her financial circumstances;

(d) not to be denied care and services because of his or her inability to pay a fee for reasons beyond his or her control.

Care Recipient Responsibilities

Care recipients also have a number of responsibilities including

General

(a) to respect the rights of care workers to their human, legal and workplace rights including the right to work in a safe environment;

(b) to treat care workers without exploitation, abuse, discrimination or harassment;

Care and services

(a) to abide by the terms of the written home care agreement;

(b) to acknowledge that his or her needs may change and to negotiate modifications of care and service if his or her care needs change;

(c) to accept responsibility for his or her own actions and choices even though some actions and choices may involve an element of risk;

Communication

(a) to give enough information to assist the approved provider to develop, deliver and review a care plan;

(b) to tell the approved provider and their staff about any problems with the care and services;

Access

(a) to allow safe and reasonable access for care workers at the times specified in his or her care plan or otherwise by agreement;

(b) to provide reasonable notice if he or she does not require home care to be provided on a particular day.

Fees

Each care recipient has the responsibility to pay any fees as specified in the agreement or to negotiate an alternative arrangement with the provider if any changes occur in his or her financial circumstances.

Challenges with CDC

Recent challenges with CDC include:

- management of the workforce as consumer demand will ebb and flow and possible redundancy of staff;
- compliance with the administrative requirements including to provide an individualised budget and monthly statements, particularly if the aged care pension changes mid-year;
- disagreements between the consumer and the Approved Provider – refer to our previous article on Consumer Directed Care - Want vs Need in the February 2015 edition of the Health Law Bulletin, available on our website; and
- ensuring that the Home Care Agreements (with the care recipient/consumer) are compliant with the Aged Care Legislation and all other laws, including the Australian Consumer Law.

Please refer to the article on Unfair Contracts in this Health Law Bulletin.

Subcontracted or brokered arrangements

Services may be provided directly by the provider, sub-contracted to another service provider (individual or organisation), or brokered through another organisation.

Regardless of how services are delivered and by whom, the Approved Provider remains responsible for service quality and meeting all regulatory responsibilities.

Subcontracting service provision to informal carers, family members or friends is not encouraged under the Home Care Packages Programme. However, it is recognised there may be no workable alternative in some areas (for example, remote parts of Australia).

With consumers choosing services, the need has arisen for Approved Providers to put in place subcontracts or brokerage agreements with subcontractors with whom they may not have a prior relationship.

Approved Providers should put a written contract in place with its subcontractors to clearly set out each party's obligation and to ensure compliance all relevant obligations under the Aged Care legislation and other legal requirements, including work, health and safety.

The Accountability Principles require an approved provider to ensure that all staff and any other person likely to have contact with care recipients have been issued with a Compliant Police Certificate or a statutory declaration which meets the requirements of the Accountability Principles.

Approved Providers will be required to manage other legal requirements, issues and risks such as privacy and work, health and safety, (including dealing with aggression), bullying and stress. Acts of aggression can occur in the home environment not only by the care recipient, but also other people living or attending the premises. The duties of an employer for work health and safety apply to subcontractors in the same way as they apply to employees. As the workers are working in a home environment (often without supervision), orientation, training, hand-over, reporting and insurance are very important.

Are you ready for the home care industry to be opened up like Uber? – *Aged Care Legislation Amendment (Increasing Consumer Choice) Act 2016 (Cth)*

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

Until 27 February 2017, CDC funding for home care is provided to places as allocated to Approved Providers via the Aged Care Approval Rounds (**ACAR**).

The Government has passed the *Aged Care Legislation Amendment (Increasing Consumer Choice) Act 2016 (Cth)*.

The reforms will be implemented in two stages.

- Stage 1 – From 27 February 2017, home care will not be subject to ACAR. The model will change from the funding and allocation of places to funding which will follow the consumer. This will allow the consumer to choose a provider that is suited to them and to direct the funding to that provider. The consumer will also be able to change their provider if they wish, including if they move to another area to live.
- Stage 2 – will integrate the Home Care Packages Programme and the Commonwealth Home Support Programme into a single care at home programme. This will simplify the way that services are delivered and funded. Stage 2 is intended to be introduced from July 2018.

  The Stage 1 changes are in three main areas:

  - funding for a home care package will follow the consumer;
  - there will be a consistent national approach to prioritising access to home care packages through My Aged Care (the Government gateway); and
  - to reduce red tape under the *Aged Care Amendment (Red Tape Reduction in Places Management) Act 2016*, which commenced on 11 February 2016.

The system will remain only open to Approved Providers. Under section 46-1 an Approved Provider is eligible for a home care subsidy if the following conditions are met:

(a) the Approved Provider must be approved under Part 2.1 of the *Aged Care Act 1997 (Cth)* (the **Act**) as a provider of home care;

(b) on the day the services are provided there is in force a home care agreement under which a care recipient approved under Part 2.3 of the Act in respect of home care is to be provided a home care by the Approved Provider through a home care service;

(c) the home care service is a *notified home care service* (which is a new concept);

(d) the care recipient is a *prioritised home care recipient*;

(e) on the relevant day the home care provided is required under the home care agreement; and

(f) the Approved Provider has agreed in the claim relating to those services on that day to deal with the care recipient's unspent home care amount in accordance with the User Rights Principles.

The concept of notified home care service is a requirement of the approved provider to notify the department of the service, the address for the service and other information as may be included in the Approved Provider Principles (likely to be included in the 2017 principles). ■

Residential Aged Care Update – Budget Cuts and ACFI Changes

By Alison Choy Flannigan, Partner

The Federal Government announced in the 2016/2017 budget[10] that it will achieve efficiencies of $1.2 billion over four years through changes to the scoring matrix of the Aged Care Funding Instrument (**ACFI**) that determines the level of funding paid to aged care providers. The Government will also reduce indexation of the Complex Health Care component of the ACFI by 50 per cent in 2016/17 and establish a $53.3 million transitional assistance fund to support providers.

These changes expand on the refinements made through the 2015/16 Mid Year Economic and Fiscal Outlook (**MYEFO**) measure titled *Aged Care Provider Funding — revision to the Aged Care Funding Instrument Complex Health Care Domain*. This measure is part of the Government's response to the continued higher than expected growth in ACFI expenditure, which has increased by a further $2.5 billion over the forward estimates since the 2015/16 MYEFO.

The ACFI is a resource allocation instrument. It focuses on the main areas that discriminate care needs among residents. The ACFI assesses core care needs as a basis for allocating funding.[11]

The ACFI focuses on care needs related to day to day, high frequency need for care. These aspects are appropriate for measuring the average cost of care in longer stay environments.[12]

While based on the differential resource requirements of individual persons, the ACFI is primarily intended to deliver funding to residential aged care providers. When completed on all residents in the facility the ACFI determines the overall relative care needs profile and the subsequent funding.[13]

The ACFI consists of 12 questions about assessed care needs, each having four ratings (A, B, C or D) and two diagnostic sections. While the ACFI questions provide basic information that is related to fundamental care need areas, it is not a comprehensive assessment package.[14]

The ACFI User Guide is available at: https://agedcare.health.gov.au/aged-care-funding/residential-care-subsidy/basic-subsidy-amount-aged-care-funding-instrument/aged-care-funding-instrument-acfi-user-guide.

The changes mean that Approved Providers need to be particularly vigilant in relation to the appropriate assessment of care needs and their claims for payment and preparing appropriate documentation should they be audited. ■

10 http://www.budget.gov.au/2016-17/content/bp2/html/bp2_expense-15.htm
11 https://agedcare.health.gov.au/aged-care-funding/residential-care-subsidy/basic-subsidy-amount-aged-care-funding-instrument/aged-care-funding-instrument-acfi-user-guide
12 Ibid
13 Ibid
14 Ibid

Information for Approved Providers of Residential Aged Care Homes on Charging Fees for Additional Care and Services in Residential Aged Care, including 'Capital Refurbishment' Type Fees

By Alison Choy Flannigan, Partner

The Government published on 2 September 2016 *Information for Approved Providers of Residential Aged Care Homes on Charging Fees for Additional Care and Services in Residential Aged Care, including 'Capital Refurbishment' Type Fees*.[15]

The Department considers that these provisions mean that providers are not able to charge fees above the maximum amount worked out under the *Aged Care Act 1997* (Cth) (the **Act**) for services or activities that are part of the normal operation of an aged care home, or are required to be delivered as part of a provider's responsibilities. Fees for 'other care or services' can also not be charged unless the resident receives a direct benefit or has the capacity to take up or make use of the services.

This differs from extra service fees that are charged for rooms within aged care homes (either individual rooms or across the home) that have been granted extra service status by the department. Extra service fees are for higher standards of food, accommodation and hotel-type services, but not for care.

The Department considers that 'capital refurbishment fees', 'asset replacement contributions' and similar fees would not be supported by the legislation where the fee does not provide a direct benefit to the individual or the resident cannot take up or make use of the services, or where the activities or services subject to the fee are part of the normal operation of an aged care home and fall within the scope of specified care and services. ■

15 https://agedcare.health.gov.au/programs/residential-care/charging-fees-for-additional-care-and-services-in-residential-aged-care-including-capital-refurbishment-type-fees

Understanding the Classification Principles – *Secretary, Department of Health* v *DLW Health Services Pty Limited* [2016] FCA 108

By Alison Choy Flannigan, Partner

Secretary, Department of Health v *DLW Health Services Pty Limited* [2016] FCA 108 is an appeal to the Federal Court of Australia against a decision of the Administrative Appeals Tribunal, concerning a decision by delegates of the Commonwealth Department of Health to reduce classification levels of aged care recipients.

The question for the Federal Court was whether or not the *Classification Principles 1997 (Cth)* purported to classify care recipients based on the care actually provided as opposed to their care needs.

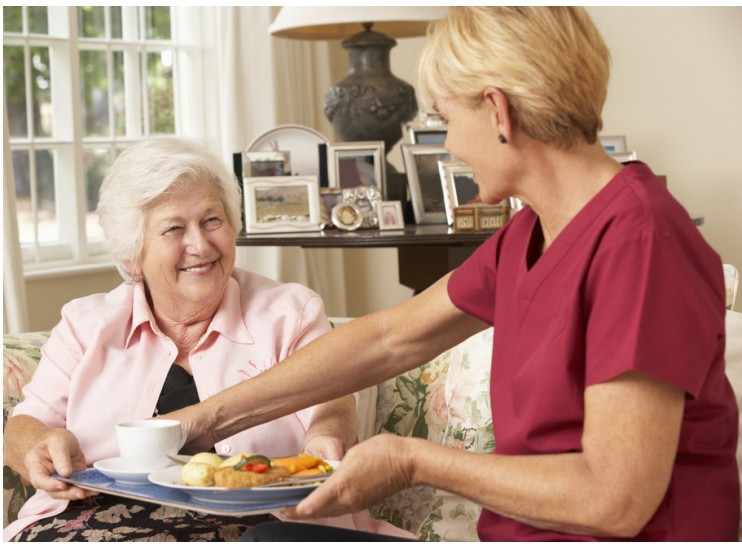
The Classification Principles determines the appropriate classification level for a care recipient being provided with residential care.

The case concerned the Secretary's decision to reduce the classification levels for the five residents of Footscray Aged Care, in relation to complex medical and therapeutic procedures. The scheme requires the Approved Provider to make an appraisal of the level of care needed by a care recipient and for the Secretary to take that appraisal into account when classifying the care recipient. However, if the classification is based on an incorrect or inaccurate appraisal or if the classification is for any other reason incorrect, the Secretary must change the classification.

There were four issues to consider:

1. The Court held that the Tribunal was correct to decide that the Minister's power to make Classification Principles is limited by a requirement under section 25-1 of the *Aged Care Act 1997 (Cth)* (the **Act**) that such principles classify the care recipient according to the level of care the care recipient needs, relative to the needs of other care recipients.
2. More importantly, the issue is whether they purport to classify the care recipients according to the treatment actually provided to the recipient.
3. A care recipient will only come within Items 4a or 4b of ACFI 12 if a Directive issued by a medical practitioner or allied health professional indicates that the treatment specified in respect of those items is to be provided (i.e. performed) by an allied health professional (or registered nurse for Item 4a). The Court held that the Tribunal made an error in allowing a care recipient to come within those items where an allied health professional delegates treatment to someone who is not an allied health professional.
4. Whether an examination of the Directives and other records before the Tribunal shows that Items 4a and 4b of ACFI 12 are satisfied in respect of the five residents? The Court allowed the appeal, set aside the decision of the Tribunal and remitted the matter to the Tribunal to decide again.

The appeal has revealed some significant inconsistencies, ambiguities and difficulties in the language of the Answer Appraisal Pack and the User Guide and is a useful example as to the complexities of Approved Providers assessing care recipients needs. ■



Improving Patient Outcomes for our Non-English Speaking Community and the Hearing Impaired - When do you need to use an interpreter in providing health services? *Biggs v George [2016] NSWCA 113; Hinton v Alpha Westmead Private Hospital [2016] FCAFC 107*

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

The requirement for clinicians to adequately communicate with their patients is well established for a number of reasons, including:

- the duty of care to appropriately treat a patient, and, in order to do so, obtain an adequate understanding of the patient's medical history and clinical needs;
- an obligation to warn of material risks as part of the duty of care: *Wallace v Kam* (2013) 250 CLR 375; *Rogers v Whitaker* (1992) 175 CLR 479;
- to obtain appropriate consent for the treatment and as a defence against assault and battery;
- best practice to obtain optimum patient outcomes;
- to discharge professional duties to engage in satisfactory professional conduct under the *Health Practitioner Regulation National Law*; and
- in order to provide services without discrimination.

The Medical Board of Australia - Code of Conduct for doctors in Australia states:

> *"An important part of the doctor-patient relationship is effective communication, including familiarizing yourself with, and using whenever necessary, qualified language interpreters or cultural interpreters to help you to meet patient's communication needs".*

There have been two recent cases which provide guidance on when an interpreter should be used, one dealing with the duty to inform of material risks and the other concerning discrimination.

Biggs v George [2016] NSWCA 113

In November 2009 Ms Sandra George, a Macedonian-speaker with a poor grasp of English, underwent an operation to remove an acoustic neuroma, a tumour on the sheath of an acoustic nerve. The operation was performed following consultations in which Ms George had been assisted by interpreters.

On the first two occasions, held at a clinic run by St Vincent's Hospital in Moree where Ms George lived, a friend translated for her. On the latter two occasions held at St Vincent's Hospital in Sydney, she was provided with an accredited interpreter. During the course of the operation an adjoining facial nerve was severed which resulted in her suffering from facial palsy. In 2012 Ms George commenced proceedings in the District Court claiming damages for negligence against the surgeon, Dr Nigel Biggs, and St Vincent's Hospital Sydney Ltd, for vicarious liability of its medical staff.

The law as concerns the duty owed by a medical practitioner to warn a patient of material risks remains that as set out in the High Court case of *Rogers v Whitaker* (1992) 175 CLR 479 which is "except in cases of emergency or necessity, all medical treatment is preceded by the patient's choice to undergo it" a choice which is "in reality, meaningless unless it is made on the basis of relevant information and advice". That is, the duty to warn a patient of a proposed treatment is to warn of all material risks which a reasonable person in the position of the patient would be likely to attach significance in choosing whether or not to undergo a proposed treatment" (*Wallace v Kam* (2013) 250 CLR 375)."

The Court Appeal stated "A correct statement of the content of the duty would have involved no more than that the medical practitioners were to take reasonable care to ensure that the material risks attending the surgical procedure were conveyed to the patient. The need for translation may involve an additional element and ….. as may be necessary for the practitioners to satisfy themselves that the substance of the information conveyed has been understood".[16]

Therefore, medical practitioners (and other clinicians) are required to be satisfied that the substance of the information conveyed has been understood and this may include being satisfied that the translator has properly conveyed the message.

In the Biggs case, the patient saw an ENT registrar. A Macedonian telephone interpreter was booked on that occasion and used via handheld telephone, there being no speaker phone available. The receiver was passed from doctor to patient and back as the conversation preceded. The doctor's notes and oral evidence were of some importance.

[16] *Biggs* v *George* [2016] NSWCA 113 at [28]

The doctor stated: *"So when I talk about my incision, I go through anything, any bits and bruises that might be any scars and then go on to problems that, a danger to the nerve, danger to hearing, balance etc. So, with my incision, I say you're going to have an incision around your eye and you're also going to have some mosquito bites on your face that might give you some little bruises. That is going to be from the facial nerve monitor. The reason we need to have a facial nerve monitor is because this tumour wraps around your facial nerve, it's one of the risks that – of removing the tumour, we're peeling the tumour off the facial nerves, that there's a danger of damage to it. The danger is most often temporary. It will recover. Sometimes it can be permanent in which case we will need to repair the nerves."*

The operation was eventually carried out. At that stage there had been no fewer than 5 occasions on which, according to the evidence of 3 medical practitioners, the claimant had been given advice concerning the risks attendant on the procedure.

The Court of Appeal held that the claimant did know and understand the risks, therefore, no causation. Claims against both defendants dismissed.

Hinton v Alpha Westmead Private Hospital [2016] FCAFC 107

In *Hinton v Alpha Westmead Private Hospital [2016] FCAFC 107*, the appellant alleged that Westmead Private Hospital had discriminated against her as an associate of a person with a disability, being her husband, in contravention of various provisions of the *Disability Discrimination Act 1992* (Cth) (the **DD Act**). The respondent, it was alleged, had refused to provide sign language interpreting services (Aslan) to the appellant's husband, who is deaf, in respect of the scheduled birth of the child of the appellant and her husband at the hospital.

Section 5 of the DD Act states:

"Direct disability discrimination

(1) For the purposes of this Act, a person (the discriminator) discriminates against another person (the aggrieved person) on the ground of a disability of the aggrieved person if, because of the disability, the discriminator treats, or proposes to treat, the aggrieved person less favourably than the discriminator would treat a person without the disability in circumstances that are not materially different.

(2) For the purposes of this Act, a person (the discriminator) also discriminates against another person (the aggrieved person) on the ground of a disability of the aggrieved person if:

(a) the discriminator does not make, or proposes not to make, reasonable adjustments for the person; and

(b) the failure to make the reasonable adjustments has, or would have, the effect that the aggrieved person is, because of the disability, treated less favourably than a person without the disability would be treated in circumstances that are not materially different.

(3) For the purposes of this section, circumstances are not materially different because of the fact that, because of the disability, the aggrieved person requires adjustments."

It was argued that the husband was not the recipient of the services.

The Federal Court decision was a judgment appealing a decision of the Federal Circuit Court summarily dismissing proceedings.

The complaint to the Australian Human Rights Commission (**AHRC**) expressly said that, although Mr Hinton was not the *"patient"*, in a case where the appellant was an expectant mother arranging to use the respondent's services for birth, *"it is unreasonable to exclude Mr Hinton as if he is somehow peripheral"*. Absent the opportunity to file any pleading to identify all of the material facts on which the appellant relied (an opportunity the primary judge denied the appellant, …), the application as filed was manifestly sufficient to raise an arguable case that the services in question included services by way of information to the husband so that he could support the appellant during the birth, confer with her as necessary, participate in the making of decisions about the treatment of the appellant and their child and, if necessary, give consent to treatment and procedures if the appellant was unable to do so. …., communication with the husband was not a separate service but a part of the service being provided to the appellant. This proposition is plainly arguable. Further, …, even if the service was being provided only to the appellant, it was equally plainly arguable that the associate provision (s 7 of the DD Act) was engaged and that the appellant was treated less favourably than a person whose associate did not have the disability in the same circumstances.

The court held that *" the primary judge's observation … that the respondent was not "present" during the discussion with the Nursing Unit Manager who was said to have informed the appellant that no Auslan interpreter would be provided appears to overlook the potential for the respondent to be found vicariously liable for the conduct of its employee …. It also overlooks the potential application of s 123 of the DD Act which provides that any "conduct engaged in on behalf of a body corporate by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority is taken, for the purposes of this Act, to have been engaged in also by the body corporate unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct" (s 123(2)). Again, it appears reasonably arguable on the face of the complaint that s 123(2) might be engaged.*

Despite the primary judge's repeated observations to the contrary, the appellant's case does not mean that, for every service sought by the appellant, an interpreter would have to be provided for the appellant's husband. It is obvious that the claim was fact dependent. The primary judge also seems to have overlooked ss 11 and 29A of the DD Act which concern unjustifiable hardship. In short, it is not unlawful discrimination in respect of the provision of a service if avoiding the discrimination would impose an unjustifiable hardship on the discriminator. No such suggestion had been made by the respondent …..

Nor can it reasonably be said that the case was about a "trifle" merely because the appellant ultimately gave birth at another hospital which provided the appellant's husband with an Auslan interpreter. The appellant did not have her child at the hospital she had proposed because it would not provide an Auslan interpreter for her husband. That circumstance gives rise to a reasonably arguable case of unlawful discrimination under the DD Act, whether it be direct or indirect discrimination. The objects of the DD Act, in s 3, are to eliminate, as far as possible, discrimination against persons on the ground of disability in the areas of "the provision of goods, facilities, services and land". It is hardly a "trifle" (and still less, equivalent to buying a "bag of chips") for a woman not to be able to deliver her baby in the hospital of her choice, merely because the hospital refuses to provide her husband with the interpreter required to ensure he can participate in the birth in the same way that a woman with a partner who can hear would be able to participate".

The case has been referred back to the Federal Circuit Court for trial.

Care should be taken when dealing with a request from a patient or a carer of a patient with a communication difficulties to ensure compliance with, amongst other obligations, discrimination laws.

Practical Tips

- Be aware of your duty of care
- Use qualified interpreters where relevant.
- Indicators of when an interpreter may be required are if the patient (or their carer or legal representative):
  - asks for an interpreter;
  - can't answer your questions easily;
  - can't repeat back information accurately;
  - has poor or limited English or is deaf; or
  - uses family or friends to communicate.
- **Practitioners must satisfy themselves that the substance of the information has been conveyed and has been understood by the patient.**
- The best way to ascertain if the information has been understood by a patient (and correctly interpreted by an interpreter) is by the "teach-back" method and to avoid leading questions or questions which invite "yes" or "no" answers. For example, under the "teach-back" method, the patient should be able to repeat back the information accurately. Rather than say "Do you understand?" say "I want to make sure that you understand. Can you tell me in your own words….?"
- If you believe that an interpreter is not correctly interpreting the message, then you should (except in the case of an emergency) re-schedule the consultation with another interpreter and inform your facility of the problem with the interpreter.
- Keep adequate notes of the consent process, what was explained.
- If relevant, use patient information sheets disclosing material risks.
- Do not rely upon family members to interpret. Patients may not wish to freely explain their condition with family members. Family members may not be bound by confidentiality and are not familiar with medical terminology.
- Do not use bilingual staff to interpret – they are not credentialed and will be diverted from their other duties.
- Public facilities must be aware of relevant policies. For example: NSW Health Policies – PD2006_053 *Interpreters – Standard Procedure for Working with Health Care Interpreters* states that:
  - NSW Legislation requires that public sector agencies and services provide equitable access to people from non-English speaking backgrounds and people who are deaf.
  - Health care interpreters are to be used in all health care situations where communication is essential.
  - Both health care providers and patients/clients have a right to request a health care interpreter.
  - Professional accredited health care interpreters provide interpreting services within the NSW public system. The service is available 24 hours a day, 7 days a week.
  - The need for an interpreter should be recorded in a prominent place on the patients/client's medical record.
  - Consent obtained without the use of a professional interpreter (e.g. a relative or friend) may not be legally valid.
  - Health care interpreters can usually provide short written translations which are directly related to the individual patient/client.
  - Where possible, requests for interpreters should be made in advance.
  - Health care interpreters are professionally trained interpreters and abide by a professional code of ethics.
  - Bilingual health care staff are not to be used as interpreters.

Interpreter services

- Public hospitals usually have an interpreter service available – refer to your State/Territory Health Department
- The Translating and Interpreter Services provides interpreting services for medical practitioners: https://tisonline.tisnational.gov.au/RegisterAgency
- Medical practitioners (defined as general practitioners and medical specialists) are eligible for the Department of Social Services' Free Interpreting Service and access to the Doctors Priority Line (DPL) when providing services that are:
  - Medicare-rebateable
  - delivered in private practice
  - provided to non-English speakers who are Australian citizens, permanent residents, Temporary Humanitarian Stay (subclass 449); Temporary Humanitarian Concern (subclass 786); Temporary Protection (subclass 785); and Safe Haven Enterprise (subclass 790) visa holders.

Update on Capacity: *Application of a Local Health District: Re A Patient Fay* [2016] NSWSC 624

By Alison Choy Flannigan, Partner, Nicholas Heinecke, Special Counsel and Alissa Burkhart, Intern

In the New South Wales Supreme Court in *Application of a Local Health District: Re a Patient Fay* [2016] NSWSC 624, Fay, a pregnant 19 year old woman with an intellectual disability with placental haematoma and progressive renal failure, was warned by her doctors that she was at significant risk of permanent cerebral damage and possibly death if her pregnancy continued. The medical advice had recommended that the pregnancy be terminated to allow more effective control of her blood pressure. It was made known that the foetus would not live if intervention occurred. She signed a consent form stating that if specific medical events were to cause impending death, then the baby would be delivered even if the baby's life was at stake. Her doctors desired to treat her immediately instead of waiting for one of Fay's nominated treatment-accepted events to occur.

The plaintiff appealed to enact the Court's *parens patriae* jurisdiction. The Court acknowledged that *parens patriae* adopts a parental protection of children and those who are incapable of making their own decisions based upon a legal disability and are in need of protection: *Marion's Case* (1992) 175 CLR 218. Although the jurisdiction is directed towards the welfare of the person involved, it is meant to be exercised only in exceptional situations and used with considerable caution. Its use must be in consideration of the adult at hand and must not infringe upon the patient's free will.

Generally, whenever there is a conflict between a capable adult's exercise of the right of self-determination, and the State's interest in the preservation of life, the right of the individual must prevail: *Hunter and New England Area Health Service v A by his tutor T* (2009) NSWCCA 242; 79 NSWLR 544; 204 A Crim R 315.

Exceptions may arise when the life of a viable foetus is at stake. If both mother and child may be saved, the choice of intervention may be clear.

Sackar J held:

- This case turns on whether Fay had the requisite capacity to exercise her undoubted right of self-determination. A relevantly capable individual can consent to any medical treatment rendering its administration lawful. Otherwise the individual's right to bodily integrity is protected by torts law.
- An adult is presumed to have capacity to consent to or refuse medical treatment unless or until that presumption is rebutted.
- There is a scale or spectrum of capacity. The nature of the decision and its importance are both highly relevant to any decision-making process and an assessement of capacity.
- If a person is unable to comprehend and/or retain information which is material to the relevant decision, in particular the consequences of the decision, or the person is unable to use and weigh the information as part of the process of making the decision, then generally the person will be seen as incapable of exercising their right of self-determination.
- Notwithstanding that an adult appears to consent to a course the usual presumption can be rebutted if a decision has been obtained by duress or undue influence.
- As per Lord Donaldson in *Re T (Adult: Refusal of Treatment)* [1993] Fam 95, when considering the effect of outside influences two aspects can be of crucial importance. First, the strength of the will of the patient. One who is very tired, in pain or depressed will be much less able to resist having his will overborne than one who is rested, free from pain and cheerful. Second, the relationship of the "persuader" to the patient may be of crucial importance. The influence of parents on their children or of one spouse on the other can be, but is by no means necessarily, much stronger than would be the case in other relationships.

In relation to this case, Fay's mother played an incredibly impactful role in the questioning of Fay. Fay's mother largely spoke for her and made her strong views known. During the questioning, it was deduced that even Fay's mother had not entirely comprehended the possible effects a stroke may have on her daughter. From Fay's lack of response and her mother's overly protective attitude, Ms Dana McMullen, solicitor, was led to believe that neither person truly understood the situation.

One of the most insightful pieces of evidence in the case was the exchange between Fay and Ms Dana McMullen solicitor, who had originally been retained to act on behalf of Fay.

This exchange endorses the "teach back" method of asking a patient to repeat back in their own words what was explained in order to ascertain whether or not they understood the consent process.

The transcript is as follows:

*"**Q.** Ms McMullen, are you able to just go through now the conversation that you had with Fay, doing your best to use the words used by each of you as the conversation progressed?*

***A.** Yes. I introduced myself to Fay as Dana. I explained to her that I was a lawyer, and that I had been asked to come and speak with her to try to understand what she wanted to have happen to her. I asked her if she knew where she was. She said yes, she was at the [redacted] Hospital. I asked her if she knew why she was at the hospital. She said: Yes, my kidneys. I asked her if she knew what was wrong with her kidneys. She said: There is a tear in my kidney. I asked her if there was anything else the doctors were worried about. She said: I don't know. I said: I know that you are pregnant. Do you know if the doctors are worried about your baby. She said: I don't know. I said: Do you know why the lawyers are here. She said: I don't know. I said: Do you know why the judge is here. She said: No. I explained to her that the Court was very worried that the right decisions were made for her, and that is why the lawyers and the judge had come to talk to her in hospital, to try to understand what she knew about what was happening for her. I asked her if she had heard any of the doctors say that she might have a stroke. She said: Yes. I said: Do you know what a stroke means. She said: Yes. I said: Can you tell me what a stroke means. She said: My aunty had one. I said: And what does that tell you about what a stroke means. She said: I don't know. I said: Do you know the doctors are worried that you might die. She said: Yes. I said: Do you know that the doctors are worried that you might bleed inside. She said: Yes. I said: And if these things happen, you might not be able to get better. Do you understand that. She said: Yes. I said: Now that I have explained that to you, can you now tell me what the doctors are worried about. She said she didn't know. She couldn't explain it to me. I said to her that if her baby was born today, it would not live. She said: Okay. I said: If you wait a few weeks, it might live, but noone is sure. She said: Okay. I said: Can you explain what I have just told you back to me. She said: No. I said: The doctors think that it is best that you don't keep your baby because if you do bad things might happen to your health and you can't get better. She said: Okay. I said: The doctors don't want you to keep your baby. Can you tell me what you think. She started to cry and asked for her mother to come in the room. I said to her that I could wait if she wanted to tell me. She continued to cry. I said: Do you want the chance to tell me what you want, or would you like me to leave. She said: I want my mother. I thanked her for her time and left."*

This confirmed that Fay had a severe lack of understanding and that her mother was the true decision-maker.

The psychiatrist recorded that she was unable to engage Fay in any discussion and formed the view that Fay was not able to demonstrate that she understood the medical condition and the various treatment choices. The psychiatrist was also of the view that Fay was not able to weigh up the various choices.

After an additional psychiatrist consulted Fay and her mother, similar conclusions were made.

The Court agreed that Fay did not adequately understand nor was capable of balancing or making an informed decision such as to permit her to refuse the treatment recommended. Intervention was lawfully executed. ■

Federal Court rules in favour of supervisors of trainee psychiatrist in claim for racial discrimination – *Maiocchi* v *Royal Australian and New Zealand College of Psychiatrists (No.4)* [2016] FCA 33

By Zara Officer, Special Counsel

Dr Maiocchi was a trainee psychiatrist on rotation at the Northside Clinic in Greenwich, NSW in the early months of 2010. During her time there, she received an unsatisfactory mid-term evaluation, therefore a remediation plan was prepared and adopted in relation to her performance. Later, a decision was made to terminate her clinical privileges at the Northside Clinic. Dr Maiocchi alleged that these actions were taken unreasonably based upon her race or ethnic origin, and were unlawful under Section 9 of the *Racial Discrimination Act 1975* (Cth) (**the Act**).

The proceedings

Proceedings were originally commenced in June 2012 in the Federal Court against numerous respondents and the proceedings gave rise to several interlocutory applications and interlocutory judgments, and four respondents remained. These were Dr Maiocchi's direct supervisor at the Northside Clinic, Dr Wilson, psychiatrist, the director of post graduate psychiatry training with the Northern Sydney Local Health District, Dr Jurd, the Royal Australian and New Zealand College of Psychiatrists (**RANZCP**) and the Northern Sydney Local Health District. The claims against the RANZCP and the Northern Sydney Local Health District were on the basis that they were vicariously liable for the acts of Dr Wilson and Dr Jurd.

The Court had to decide whether Dr Wilson at Northside Clinic contravened Section 9 of the Act by basing his actions on Dr Maiocchi's race, descent or national or ethnic origin in relation to:

(a) his preparation and adoption of a mid-term evaluation in relation to Dr Maiocchi;

(b) his request for a remediation plan for Dr Maiocchi; and

(c) his allegations of unsatisfactory performance in relation to her work in a letter to Dr Jurd in May 2010.

Further, the Court considered whether Dr Jurd contravened Section 9 of the Act by basing his actions on Dr Maiocchi's race, descent or national or ethnic origin in relation to:

(a) preparing and adopting a remediation plan in relation to Dr Maiocchi;

(b) his alleged acceptance at face value of the letter from Dr Wilson concerning unsatisfactory performance; and

(c) withdrawing Dr Maiocchi's clinical privileges.

Background

Dr Maiocchi immigrated to Australia in April 1990 from Argentina. She qualified in Argentina as a medical doctor in 1977, and as a medical specialist in radiation oncology in 1994. Dr Maiocchi became an Australian citizen in mid-1993. Spanish was her first language and she spoke that language with her husband at home, but her two children had English as their first language. Dr Maiocchi's English language communication skills were an important issue in the proceedings.

Dr Maiocchi attained full registration as a medical doctor in Australia in 2004. In 2005 Dr Maiocchi was admitted to the RANZCP as a trainee in psychiatry and she also undertook a Master's Degree in psychiatry with the NSW Institute of Psychiatry.

The claims

The events giving rise to the proceedings generally occurred during the period March to May 2010 when Dr Maiocchi was working as part of her training as a registrar in psychiatry at the Northside Clinic. By that time she had successfully completed 9 rotations as a psychiatry trainee.

Dr Maiocchi was given an unsatisfactory mid rotation report and a remediation plan was prepared requiring her to "study English, particularly spoken language skills, moderate her accent, as well as read lowbrow magazines, thereby increasing fluency in local vernacular", amongst other matters. Dr Maiocchi argued these actions were discriminatory.

Dr Maiocchi argued that Dr Wilson's letter and the withdrawal of her clinical privileges was based on her status as an overseas trained doctor.

The Respondents strongly denied Dr Maiocchi's claims that they had discriminated against her on grounds of her race, descent, national or ethnic origins.

The findings

On 5 February 2016 Justice Griffiths delivered a detailed judgment setting out the extensive evidence provided to the Court at the hearing. Justice Griffiths accepted that there were reasonable explanations for the actions of the respondents, including withdrawal of clinical privileges, based on Dr Maiocchi's clinical performance at the Northside clinic.

The Court accepted that Dr Wilson prepared the mid-term evaluation, and requested a remediation plan as a means to address the relevant performance issues, and for Dr Maiocchi to successfully complete her traineeship. The Court found that Dr Wilson's actions were not motivated by her ethnic or national origins.

The Court accepted that Dr Jurd's role in drafting and finalising the remediation plan was directed at improving Dr Maiocchi's oral communication skills to a level that was required for a trainee psychiatrist. This was reasonable and appropriate in the context of the importance of communication skills in psychiatry, and not motivated by Dr Maiocchi's ethnic or national origins.

The importance of communication skills in the practice of psychiatry

The Court accepted expert evidence that psychiatrists working in Australia require a high degree proficiency in English in a multi-disciplinary setting, to communicate with patients, colleagues, staff, carers and family members. Dr Maiocchi had obtained certificates of completion from the NSW Institute of Languages in 1991 and had passed the Australian Medical Council examinations in English. Dr Maiocchi demonstrated sufficient communication and language skills for the purposes of her various professional qualifications including her Masters Degree, however, the Court accepted evidence from Dr Jurd and Dr Wilson and from an independent expert psychiatrist, that competency in these areas was not sufficient for the purposes of becoming a qualified psychiatrist. Psychiatrists require communication and language skills of a high order, from high powered professional English, through to fluency in local vernacular to deal with a range of patients of varying socio-economic backgrounds and educational level.

The outcome

Justice Griffiths found Dr Maiocchi failed to establish to the relevant standard the allegations she made against Dr Wilson and Dr Jurd for racial discrimination under Section 9 of the Act. It was unclear that any complaint of indirect discrimination was pressed, however, if it were, it would be rejected. Dr Maiocchi failed to identify any requirement or condition imposed on her by Dr Wilson, or by Dr Jurd which she could not comply with, which was not reasonable in all the circumstances.

Similarly, Dr Jurd's acceptance of Dr Wilson's letter of complaint and Dr Jurd's involvement in the decision to terminate Dr Maiocchi's clinical privileges at the Northside Clinic were found to be not based on racial discrimination.

In the absence of any adverse findings with respect to Drs Wilson or Jurd, no issue arose as to the vicarious liability of the RANZCP or the Northern Sydney Local Health District.

Dr Maiocchi's application was dismissed with costs and no damages were awarded, and nor would damages have been awarded if Dr Maiocchi had succeeded in her case.

Holman Webb acted for Dr Wilson in this matter. ■

What you need to know about Medical Cannabis: *Narcotic Drugs Amendment Act 2016* (Cth)

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

Cannabis, as a narcotic, is currently regulated under a myriad of Commonwealth and State laws, including the following:

- *Therapeutic Goods Act 1989 (Cth)*;
- *Narcotic Drugs Act 1967 (Cth)*;
- State and Territory laws, including the *Drug Misuse and Trafficking Act 1985 (NSW)*;
- State and Territory laws which deal with poisons and therapeutic goods, such as *Poisons and Therapeutic Goods Act 1966 (NSW)*; and
- *Access to Medicinal Cannabis Act 2016 (Vic)*.

Cannabis is currently a drug listed in Schedule 9 (Prohibited Substances) of the Poisons Standard, except:

(a) when separately specified in the Schedules; or

(b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinol and products manufactured from such fibre.[17]

Prohibited Substances are substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.[18]

There are currently limited legal ways of accessing medical canabis including:

- with Commonwealth and/or State approval and therefore registration in the Australia Register of Therapeutic Goods (**ARTG**) (which Sativex has obtained, currently for limited treatment of spacicty); and
- for clinical trials under the existing TGA exemption for experimental uses and approval under State/Territory Drug Misuse and Trafficking legislation If approval is given, it is subject to strict conditions as to handling, storage, labelling, packing and record of receipt of disposition.

Whilst under the *Therapeutic Goods Act 1989 (Cth)* there are mechanisms in place to access medicinal cannabis products, due to cultivation and processing restrictions, trial products are ordinarily sourced from international suppliers.

The Commonwealth Government has passed the *Narcotic Drugs Amendment Act 2016*, which, upon full commencement, will amend the *Narcotic Drugs Act 1967 (Cth)*.

The *Narcotic Drugs Amendment Act 2016 (Cth)* sets out:

- a licensing and permit scheme which regulates the cultivation of cannabis plants and the production of cannabis and cannabis resin. Cultivation and production, and related activities, under the scheme are for medicinal purposes or for research relating to medicinal cannabis;
- regulates a cannabis research licence;
- a separate licence and permit scheme which regulates the manufacture of the drug; and
- authorised inspectors have monitoring, inspection and enforcement powers to ensure that the Act is complied with.

Further information is available on the website of the Commonwealth Department of Health, Office of Drug Control at: https://www.odc.gov.au/qa ■

[17] *Poisons Standard*, July 2016
[18] ibid

Compliance Lessons for Pharmaceutical and Medical Device Companies - Misleading and deceptive conduct in advertising pharmaceuticals – The Neurofen Case - *Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Limited (No 4)* [2015] FCA 1408

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

Most readers of this article would be familiar with the Nurofen specific pain products, each being labelled Nurofen Back Pain, Period Pain, Migraine Pain, or Tension Headache, as these products have been marketed in that manner in Australia since about 2006. Most readers would also appreciate that Nurofen, or for that matter ibuprofen lysine, is very effective at treating these types of pain.

In *Australian Commission and Consumer Commission v Reckitt Benckiser (Australia) Pty Limited (No 4)* [2015] FCA 1408, the Federal Court held that Reckitt Benckiser (Australia) Pty Limited (**Reckitt Benckiser**), in the form of the above packaging:

- engaged in conduct that is misleading or deceptive, or is likely to mislead or deceive, in contravention of section 18 of the Australian Consumer Law (**ACL**) which is Schedule 2 to the *Competition and Consumer Act 2010* (Cth); and
- engaged in conduct that is liable to mislead the public as to the nature, the characteristic or the suitability for their purpose of the products in the Nurofen Specific Pain Range within the meaning of section 33 of the ACL,

by representing that each product in the Nurofen Specific Pain Range:

- was specifically formulated to treat the particular type of pain specified on the packaging relevant to that product;
- solely or specifically treated the particular type of pain specified on the packaging relvant to that product,

when in fact each contained the same active ingredient, the Australian Register of Therapeutic Goods (ARTG) approved the same indications for the range, each product was of the same formulation and no product in the range was any more or less effective than the others.

Further, and not helpful for the defence of the Nurofen case, the Nurofen website contained a product comparison page with headings like "relieve pain with the right types of pain medication". The website questionnaire then directed users to a recommendation for one of the various specific pain relief products. The website was also found to be conduct in contravention of sections 18 and 33 of the ACL in the same way as the packaging.

Orders were made for Reckitt Benckiser to:

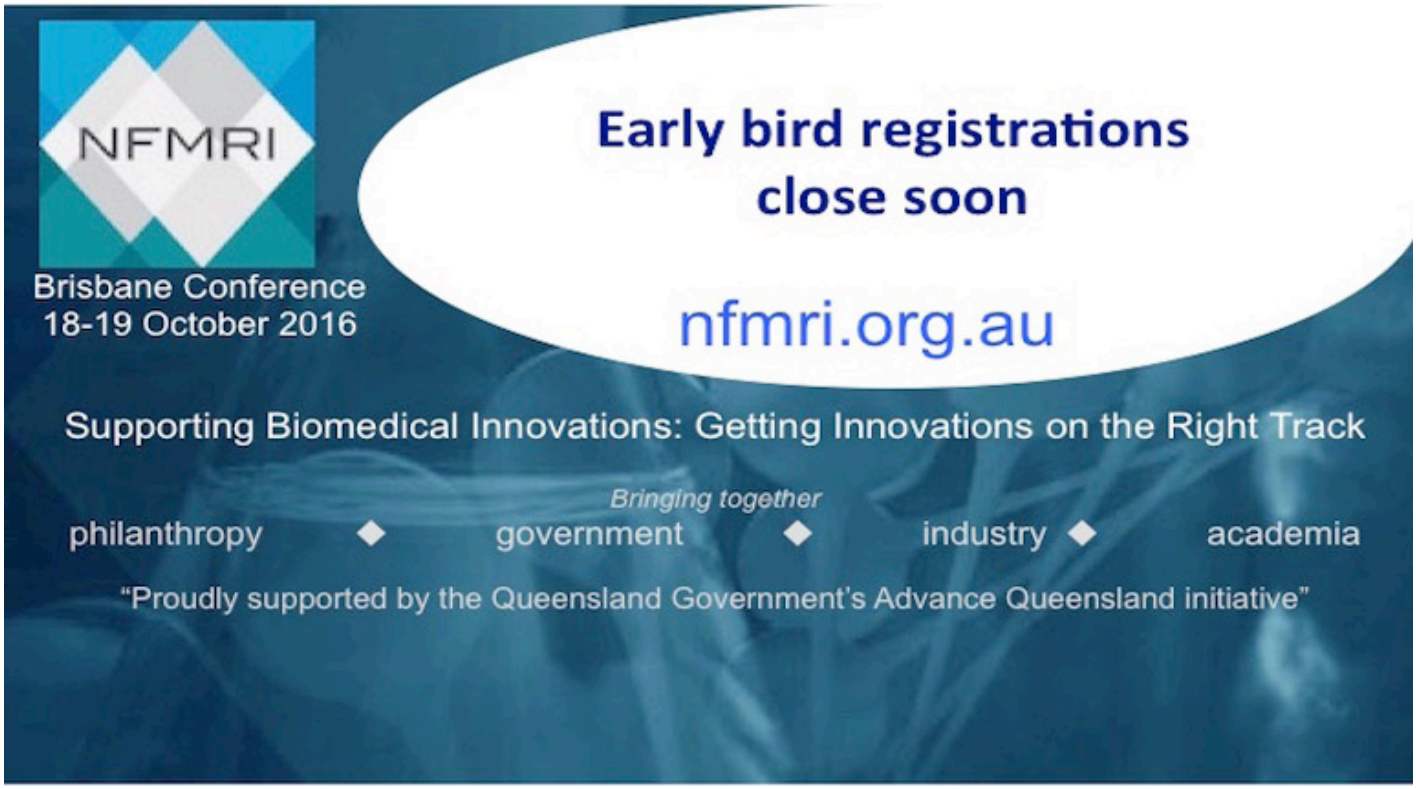
- be restrained from advertising their products in such a manner;
- to publish corrective notices;
- to comply with a compliance program, including:
  - to appoint a compliance officer;
  - to instruct the compliance officer to conduct a consumer protection law risk assessment;
  - to prepare a risk assessment report;
  - to issue a compliance policy;
  - ensure that the Compliance Program includes a consumer protection law complaints handling system capable of identifying, classifying, storing and responding to consumer protection law complaints;
  - engage in staff training;
  - ensure that the Compliance Officer reports to the Board and/or senior manager every 12 months on the continuing effectiveness of the Compliance Program;
  - provision to the ACCC of the Compliance Policy, an outline of the Complaints Handling System and Staff training materials and induction materials; and
  - implement promptly and with due diligence any recommendations of the ACCC.

This case is a timely reminder of the importance of compliance with not only the Australian Consumer Law but also the Therapeutic Goods Advertising Code (**Code**).

Importantly, under the Code an advertisement for therapeutic goods must comply with the statutes and common law of the Commonwealth, States and Territories (clause 4(1)(a)), such as the ACL. The Code approaches the test of whether an advertisement is not in conformity with the Code in terms of the "probable impact upon the reasonable person to whom the advertisement is directed".

Clause 4(2)(c) of the Code requires that an advertisement "must not mislead, or be likely to mislead, directly or by implication through emphasis, comparisons, contrasts or omissions", which adding the test of probable impact upon the reasonable person, greater care when advertising therapeutic goods is required than non-therapeutic goods subject only to the ACL.

This case highlights the type of compliance measures each and every pharmaceutical and medical device company should already have in place. Often, it is better to have an independent review of compliance on a periodic basis. The Holman Webb Health, aged care and life sciences team can provide a life sciences compliance programme, and training programme for staff, for a fixed fee. A compliance training session is offered to existing clients for no charge as a value add. For further information, please contact Alison Choy Flannigan or Nicholas Heinecke.



Holman Webb proudly provides pro-bono legal services to the National Foundation for Medical Research and Innovation

Misuse of market power – Relevance to hospital and aged care operators

By Alison Choy Flannigan, Partner

Private hospital operators conduct their business in a competitive environment and competition laws can affect how they interact with their competitors and other organisations such as private health insurers, pharmaceutical companies, medical device companies and medical practitioners.

The *Competition and Consumer Act 2010 (Cth)*[19] (the **Act**) prohibits a number of restrictive trade practices, including misuse of market power, anti-competitive contracts, price-fixing and secondary boycotts affecting competition.

Every private hospital operator must be aware of these obligations and confirm that it has policies and procedures in place to ensure compliance with the Act, as a breach (as stated in s.76 of the Act) in the case of a corporation can result in penalties up to $10 million, the value of the benefit attributable to the breach or 10% of annual turnover (whichever is the greatest). For individuals, the penalty can be up to $500,000 and the individual can be disqualified from managing a corporation. In addition, damages and injunctive remedies may be available.

Section 46 – Misuse of Market Power

Section 46 states that *"a corporation that has a substantial degree of power in a market shall not take advantage of that power in that or any other market for the purpose of:*

(a) eliminating or substantially damaging a competitor of the corporation or of a body corporate that is related to the corporation in that or any other market;

(b) preventing the entry of a person into that or any other market; or

(c) deterring or preventing a person from engaging in competitive conduct in that or any other market…."

The contravention of s.46 is "not merely the co-existence of market power, conduct and proscribed purpose, but a connection such that the firm whose conduct is in question can be said to be taking advantage of its power".[20]

What is market power?

Market power is the power to behave in a market in a manner not constrained by the competitors in that market for a sustained period. For example, being able to raise prices above supply cost without losing customers.

Example of misuse of market power

An example of misuse of market power is when the sole Australian manufacturer of a sterile fluid, being an essential product, tendered supply to public hospitals on a bundled basis with other fluids, where the price differential between the item by item price and its bundled price was substantial. This allegedly damaged competitors selling the other fluids: *ACCC* v *Baxter Healthcare Pty Limited* (No 2).[21]

What changes are proposed?

On 31 March 2015, the Federal Government released the final report of the *Competition Policy Review* (the **Review**).[22] The Review recommended substantial changes to s.46.

The Review commented that the existing s.46 was not reliably enforceable and permits anti-competitive conduct.

The Review recommended that s.46 be *"reframed to prohibit a corporation that has a substantial degree of power in a market from engaging in conduct if the proposed conduct has the purpose, or would have or be likely to have the effect of substantially lessening competition in that or any other market."*

Such a reframing would allow the provision to be simplified.

The review also made recommendations in order to mitigate concerns about inadvertently capturing pro-competitive conduct. The review recommended that authorisations (by the ACCC) should be available in relation to s.46 and that the ACCC should issue guidelines.

The Review included the following proposed wording for s.46(1):

"A corporation that has a substantial degree of power in a market shall not engage in conduct if the conduct has the purpose, or would have or be likely to have the effect, of substantially lessening competition in that or any other market…"

The recommendations met with some opposition. The Government announced in its response *Australian Government Response to the Competition Policy Review* in November 2015 that it would consult further on the reform and has decided to accept the Review recommendation in full *Prime Minister of Australia – Joint Media Statement: Fixing Competition Policy to Drive Economic Growth and Jobs* 16 March 2016. At the time of writing this article, the draft legislation has not been released.

19 *Competition and Consumer Act 2010 (Cth)* 1974

20 See *Melway Publishing Pty Ltd* v. *Robert Hicks Pty Ltd* (2001) 205 CLR 1

21 *ACCC* v. *Baxter Healthcare Pty Limited* (No.2) [2008] FCAFC 141; (2008) 170 FCR 16, 249 ALR 674

22 Competition Policy Review – Also known as the *Harper Review*

What are the key differences?

The proposed changes:

1. remove the 'take advantage' test – so the applicant will no longer have to prove that the respondent used its market power (and not some other power);
2. shift 'for a purpose' to 'has the purpose, or would likely to have the effect' of substantially lessening competition – so the applicant will no longer have to focus on the purpose for which the market power was used, rather the effect of the conduct;
3. move from a focus on 'damage to a competitor' to a focus on 'substantially lessening competition'; and
4. adding further factors for a court to take into account and matters aimed at reducing uncertainty.

The amended s.46 is designed to make it easier to enforce penalties and to prohibit a breach of misuse of market power by large companies with market power (such as large private health insurers) from engaging in a misuse of market power which affects competitors (other private health insurers) and non-competitors in other markets (such as private hospital operators). It is not until the legislation is passed and tested that we will be able to measure its true effect. ■

It's Time to Review and Update your Standard Form Contracts

Unfair Contract Terms in Consumer Contracts and Small Business Contracts – Australian Consumer Law – *Treasury Legislation Amendment (Small Business and Unfair Contract Terms) Act 2015*

By Alison Choy Flannigan, Partner

Unfair Terms of Consumer Contracts

Section 23 of the *Australian Consumer Law* (**ACL**), which is contained within Schedule 2 to the *Competition and Consumer Act 2010 (Cth)* states that a term of a consumer contract will be void if the term is unfair and the contract is a standard form contract.

What is a Consumer Contract?

A consumer contract is a contract for a supply of goods or services or a sale or grant of an interest in land to an individual whose acquisition of the goods, services or interest is wholly or predominantly for personal, domestic or household use or consumption.

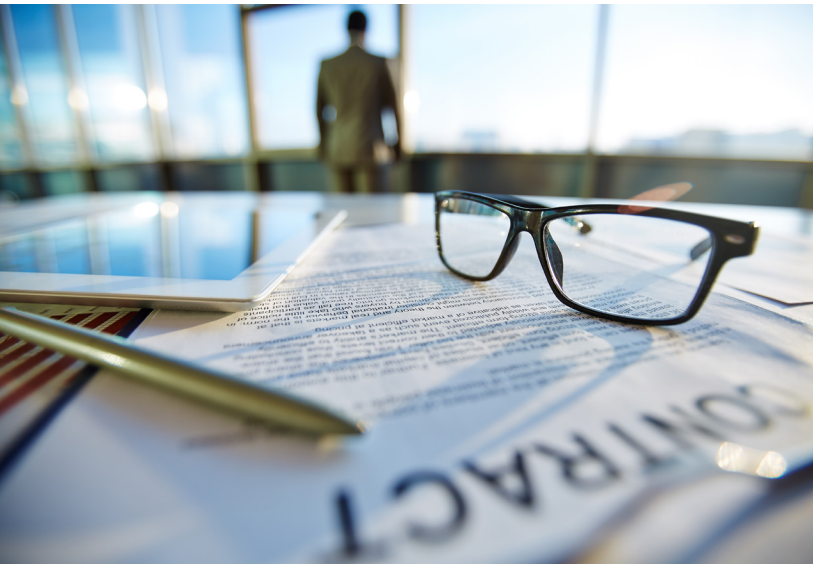
A contract with a consumer for the provision of health services, aged care services, pharmaceuticals, medical devices and/or retirement living services would be a consumer contract.

What is a Standard Term Contract?

If a party alleges that a contract is a standard term contract, it will be presumed to be one unless the other party proves otherwise: ACL, section 27.

In determining whether or not a contract is a "standard term contract", a court may take into consideration matters it thinks relevant, including:

- Whether one of the parties has all or most of the bargaining power relating to the transaction;
- Whether the contract was prepared by one party prior to discussions;
- Whether the other party was required to accept or reject the contract;
- Whether a party was given an effective opportunity to negotiate the terms of the contract; and
- Whether the contract takes into account specific characteristics of the other party.



What is Unfair?

A term in a contract will only be unfair if three tests are satisfied: ACL, section 24(1), namely if the term:

- causes a significant imbalance in the parties' rights and obligations under the contract;
- is not reasonably necessary to protect the legitimate interests of the party advantaged by the term; and
- causes financial or other detriment to a consumer if it were relied on.

What is an example of an unfair contractual term?

Section 25 of the ACL sets out examples of unfair terms, including:

(a) one party (but not the other) can:

(i) avoid or limit the performance of the contract;

(ii) terminate the contract;

(iii) penalise for a breach or termination of the contract;

(iv) vary the terms of the contract or the upfront price payable or the services to be supplied;

(v) renew or not renew the contract;

(vi) assign the contract to the detriment of the other without the other's consent; or

(b) terms that limit or has the effect of permitting:

(i) one party's right to sue another party – this applies to limitation of liability clauses; or

(ii) one party's vicarious liability for its agents.

Small Business Contracts

From **12 November 2016** under the *Treasury Legislation Amendment (Small Business and Unfair Contract Terms) Act 2015*, the unfair contract provisions will be extended to small business contracts.

These will include small businesses to whom health and aged care providers subcontract services.

What is a Small Business Contract?

A contract is a "small business contract" if:

(a) the contract is for a supply of goods or services, or a sale or grant of an interest in land; and

(b) at the time the contract is entered into, at least one party to the contract is a business than employs fewer than 20 persons (including casual employees who are employed on a regular and systemic basis); and

(c) either:

(i) the upfront price payable under the contract does not exceed $300,000; or

(i) the contract is more than 12 months and the upfront price payable under the contract does not exceed $1 million.

Excluded Terms

The provisions do not apply to terms that:

- define the subject matter of the contract, such as the product or service to be supplied;
- set the upfront price payable under the contract; or
- is required or permitted by another law.

Excluded Contracts

There are some contracts to which the unfair contracts provisions do not apply including:

- financial services or for financial products, including insurance contracts, however, private health insurance contracts are covered;
- constitutions of companies; and
- contracts for the shipping of goods.

Managing the Threat of Terrorism In Public Institutions such as Hospitals and Aged Care Facilities

By Rachel Sutton, Partner

Unfortunately, we live in a world today where terrorist attacks have become far too common. Counter-terrorism strategies and tactics are rightly in the consciousness of governments, employers and the public at large in the wake of attacks in Kenya, Beirut, Paris, Nice and many other locations around the world which experienced massive losses of life by the actions of extremists (not to mention the numerous shootings, bombings, and bio-attacks that continue to take place). In August 2016 there was a terrorist attack on a Pakistan hospital which killed more than 50 people.[23] Locally, we have had our own challenges with the loss of life arising from the Martin Place Siege and attack on NSW Police Headquarters in Parramatta.

Security challenges in the workplace have, however, existed for centuries. Work Health and Safety (**WHS**) laws require employers to develop strategies to eliminate or control these risks. This responsibility applies equally to the security-related risks and threats.

The best method for addressing workplace violence is to prevent it from occurring in the first place. Violence in the form of terrorism can take many forms and occur virtually anywhere at any time, so public institutions such as hospitals and aged care facilities must be diligent in taking all possible measures to avoid such incidents at their worksites, and have a risk management framework in place should they occur.

A terrorist act is not defined in the WHS legislation[24] however it is defined in the *Terrorism (Commonwealth Powers) Act 2002 (NSW)*[25] as:

(a) action that is done or the threat is made with the intention of advancing a political, religious or ideological cause; and

(b) the action is done or the threat is made with the intention of:

(i) coercing, or influencing by intimidation, the government of the Commonwealth or a State, Territory or foreign country, or of part of a State, Territory or foreign country; or

(ii) intimidating the public or a section of the public.

that

(a) causes serious harm that is physical harm to a person;

(b) causes serious damage to property;

(c) causes a person's death;

(d) endangers a person's life, other than the life of the person taking the action;

(e) creates a serious risk to the health or safety of the public or a section of the public; or

(f) seriously interferes with, seriously disrupts, or destroys, an electronic system including, but not limited to:

(i) an information system;

(ii) a telecommunications system;

(iii) a financial system;

(iv) a system used for the delivery of essential government services;

(v) a system used for, or by, an essential public utility; or

(vi) a system used for, or by, a transport system.

The most common types of terror attacks that may occur at a workplace include:

- **Fires and Explosions:** Caused by arson or an explosive device on a targeted location or building. Although employers cannot be expected to reasonably identify and attempt to control these hazards, they should have effective fire prevention plans in place and provide employees with action plans to safely respond to threats and incidents;
- **Bioterrorism:** The intentional use of micro-organisms to bring about ill effects or death to humans, livestock, or crops. Employees who receive materials and packages to their worksites must be trained to identify suspicious substances and minimize exposures in the work environment; and
- **Radiological Dispersal Devices (RDD):** Known as "dirty bombs," these consist of radioactive material combined with conventional explosives. Their purpose is to disperse the radioactive chemicals over a large area, killing those in the immediate area and causing panic in the target population.

A comprehensive framework to risk management is imperative to managing the threat and risk of terrorist acts. The risk management process involves the following:

- **Establishing Context** – Looking at the environment the organisation operates in to ensure that the strategies to mitigate risk are cost effective, operationally effective and appropriate;
- **Identification** – Identifying all security risks which the framework will be responsible for assessing and mitigating;
- **Analysis** – Assessing the likelihood and consequences of each risk occurring. This involves looking at worksite vulnerabilities, recognized threat, and anticipated consequences of the event. Keep in mind that although many vulnerable locations are typically identified as public spaces, they are still the worksites for thousands of employees. These factors include the extent to which a site:
  - Uses, handles, stores, or transports hazardous materials;
  - Provides essential services;
  - Has a high volume of pedestrian traffic;
  - Has limited means of egress, such as a high-rise complex; or underground operations;
  - Has a high volume of incoming materials;
  - Is considered a high profile site;
  - Is part of the transportation system;

[23] http://www.un.org/apps/news/story.asp?NewsID=54641#.V8ZHoa2tH9M

[24] *Work Health and Safety Act 2011* (NSW) and *Work Health and Safety Regulation 2012* (NSW)

[25] Schedule 1 of the *Terrorism (Commonwealth Powers) Act 2002 (NSW)*

- **Evaluation** – Involves the application of metrics to determine relative values for each risk category and is often achieved using a risk analysis matrix (e.g. Very Low, Low, Medium, High and Critical);
- **Treatment** – Involves determining the most appropriate strategy to mitigate the risk by applying different treatment options such as accepting, avoiding, reducing or transferring the risk;
- **Communication and Consultation** – Stakeholder consultation is integral at each stage of the process and ensures and effective gathering of information and assistance with mitigating any identified risks. Consultation with local and federal agencies to discuss potential threats will assist so that they can work with you to better plan your preparedness and response procedures; and
- **Monitoring and Reviewing the Risks** – Periodic assessments and checks should be undertaken to ensure changes in the risk environment are reflected in the security measures and for public institutions assessments may need to be made more frequently than other employers.

Preventative measures that may be considered as part of a comprehensive approach include:

- Pedestrian and vehicle access controls;
- On-site security guards;
- Appropriate surveillance systems;
- Emergency response plan and lock down capabilities - It is critical to implement an emergency response plan which facilitates and organizes employer and employee actions during workplace emergencies in the event of a terror incident. Employees should be trained to understand their roles within the plan, conduct regular fire and evacuation drills so that employees know their best way out of the worksite and where to find a safe space, and providing accessible safety equipment such as fire extinguishers and masks;
- Human resources and employee assistance programs – a Human Impact Team that is trained and prepared to specialise in the human side of crisis response and a Family Assistance Program Team as well as temporary arrangements for employees such as personal protection coaching, time off, personal security provisions, flexible work schedule and relocation to another facility may be included in these plans;
- Premises hardening (i.e. locks and other controlled-access systems that keep out unwanted intruders);
- Employee workplace violence orientation;
- Hostility Management Training;
- Threat notification system – employees need to know that they share responsibility for safety and to report threats promptly and who to and what will happen next;
- Threat Response Team – Ideally you should also have a trained, multidisciplinary Threat Response Team to plan for, investigate, assess and, where possible, diffuse threatening situations. Employees should know that the organisation has a team trained to respond to significant threats;
- Crisis communications – these need to be managed to and from affected stakeholders to ensure appropriate personnel are prepared to respond effectively; and
- Insurance cover for such events.

A terror attack can be catastrophic to an organisation financially, on the employees and to its reputation. Although there is no way to completely eliminate the threat of a terrorist attack taking place at a worksite, organisations that are effective in managing the risk are more likely to be prepared for such an event were it to take place and minimise the loss of life as result and less likely to be accused of being negligent for failing to prepare and plan for it.

What do you do if a patient disputes the accuracy of their medical records? *BMS v St Vincent's Health Network Sydney Limited [2015] NSWCATAD 177*

By Alison Choy Flannigan, Partner

What happens if a patient, particularly a mental health patient, does not agree with their medical record?

Section 11(2) of the *Health Records and Information Privacy Act 2002 (NSW)* requires a health service provider organisation to whom the Act applies to comply with the Health Privacy Principles stated in that Act." There are similarities between the NSW legislation and the Commonwealth *Privacy Act 1988* (Cth) which applies to private sector health and aged care providers nationally.

In the case of *BMS v St Vincent's Health Network Sydney Limited* [26] BMS (a pseudonym) was hospitalised in April 2013. A note was made in the progress note that BMS had stated a fact. BMS denied making the statement and applied for the deletion of the statement from the medical record.

HPP 8 requires an organisation, at the request of the individual to whom the information relates, to make appropriate amendments (whether by way of corrections, deletions or additions) to ensure that the health information is accurate. If an organisation is not prepared to amend the health information in accordance with a request, the organisation must take such steps as are reasonable to attach to the information, in such a manner as is capable of being read with the information, any statement of the amendment sought provided by that individual.

In the circumstances, two issues arose for the hospital:

1. Was the information accurate?
2. If so, was it necessary to retain that information in the medical record?

Sometimes it is necessary to retain information in the medical record in order to accurately treat the patient or for documentation retention purposes, for example, under the *State Records Act 1998 (NSW)*.

In this case:

1. In the hospital's opinion, the information was accurate; and
2. the respondent was required to retain the medical record, however, was prepared to seal the record (restricting access), attaching a copy of a letter by the applicant to the medical record and making a notation against the relevant record.

Under oath, the applicant denied having made the statement.

The Tribunal noted that nothing in HPP8 requires an agency to amend information that it considers accurate, however, in those circumstances it must attach to the information any statement provided by the applicant of the amendment sought. It follows that a finding by the Tribunal that the information is inaccurate is a necessary pre-condition to a consideration of the appropriate amendment, whether by correction, deletion as sought by the applicant, or additions.

The hospital submitted the affidavit of the treating doctor, Dr Millard and relied upon contemporaneous progress notes.

At the hearing Dr Millard gave a detailed description of the room in which the review took place and testified that the notes were contemporaneous. His role at the psychiatric review was to take notes. His usual practice is to write down what is said as it is said. In his affidavit, Dr Millard noted that the statement appeared amongst other notations of episodes of a particular genius and that he believed the notation was of a statement made by the applicant during the review.

In summary, the applicant denied the review took place and gave evidence by reference to the nursing progress notes that she was elsewhere.

The progress note was a contemporaneous note containing either paraphrasing or direct quotes of statements made by the applicant during the review. The Tribunal accepted the submissions of the respondent that the notes were of things said at the time and that they were taken during a continuous period of time during the interview and comprise a distinct three and a bit pages in the progress notes without interruption. The respondent also submitted that the applicant has made no complaint about the accuracy of the rest of the notes.

The Tribunal was comfortably satisfied that the statement in the medical progress notes was an accurate record of the interview. It followed that there is no obligation for the agency to amend the record. It does, however, have an obligation to take steps as are reasonable to attach to the progress notes any statement provided by the applicant of the amendment sought. The Tribunal was satisfied that the respondent had met the obligation contained in HPP8. No further action was required to be taken by the respondent.

Holman Webb acted for St Vincent's Health Network in the above matter.

[26] *BMS* v *St Vincent's Health Network Sydney Limited* [2015] NSWCATAD 177 (J Kinross, Senior Member)

Can a health or aged care provider be liable if their subcontractor does not comply with the Fair Work Act?

By Rachael Sutton, Partner

In a tighter fiscal environment with reduced budgets, health and aged care providers are taking steps to focus their business on their core competency - the delivery of health and/or aged care services and are exploring outsourcing.

Health and aged care providers are outsourcing not only ancillary tasks but also engaging contractors to provide additional clinical resources, including nurse agencies. Outsourcing arrangements can improve financial results by reducing administrative costs and increasing revenues, efficiency and service quality. Areas that are strong candidates for outsourcing include revenue cycle services, human resources, billing, finance and administration, information technology, laundry, housekeeping, food services, security and some clinical services.

Selecting the proper scope of services to be outsourced is the first and sometimes the most difficult decision for the outsourcing team. The decision involves many considerations such as:

- What is the goal of the outsourcing arrangement?
- What are the risks?
- Are there experienced outsourcing providers that can effectively provide the service?
- Does it give the organisation a competitive advantage?
- How much costs savings can be achieved?
- What internal expertise will be retained to effectively manage the outsourced service?
- Are there legal restrictions to outsourcing the function?

Although outsourcing can have many benefits, it will fail if it is not done for the right reasons and managed successfully. Worse still, it can potentially expose the organization and senior staff and executives to claims for underpayment or accessorial liability in respect to breaches by the outsourcing vendor in respect to employee entitlements owed by the subcontractor under the *Fair Work Act, 2009* (Cth) (**FWA**). This would include public sector hospitals using employees of contractors whose terms and conditions are subject to the FWA.

There have been a number of recent prosecutions by the Fair Work Ombudsman (**FWO**) that provide a warning for organisations for whom contracting is a means of engaging labour.

The FWO is involved where the terms of engagement of a worker, supposedly as a contractor or engaged as an employee by a contractor, results in payment of remuneration less than that which would have been payable had the worker been engaged as an employee.

Accessorial liability issues for individuals also arise in relation to sham contracting, underpayment, and breaches of the National Employment Standards (**NES**) under the FWA.

Section 550 of the FWA provides:

"Involvement in contravention treated in same way as actual contravention

(1) A person who is involved in a contravention of a civil remedy provision is taken to have contravened that provision.

*(2) A person is **involved in** a contravention of a civil remedy provision if, and only if, the person:*

(a) has aided, abetted, counselled or procured the contravention; or

(b) has induced the contravention, whether by threats or promises or otherwise; or

(c) has been in any way, by act or omission, directly or indirectly, knowingly concerned in or party to the contravention; or

(d) has conspired with others to effect the contravention".

There may be circumstances where you are deemed to be "involved" in a breach of the FWA. Where this happens, you will be taken to have personally engaged in a contravention, which means that you can potentially be fined. This is in addition to any fines imposed on the actual employer.

For the organization or you to be "involved" in a contravention of the FWA, you must have had knowledge of the essential facts constituting the contravention; you must have been knowingly concerned in it; and you must have been an intentional participant in the contravention based on your actual knowledge.

A key point to remember is that you don't even have to know that the actions in question constituted a contravention for you to be legally considered "involved" in that contravention.

You are more likely to be "involved" in a contravention if you are involved in the day-to-day operations of the employer and have a higher degree of control. However, you need not hold any special or senior position - anyone can be liable.

On Friday, 27 May 2016, the FWO spoke about its increasing focus on accessorial liability stating:

"We are pushing the boundaries of the accessorial liability provisions contained in the FW Act. This is how Coles ended up in court. So far this financial year nearly every matter we have filed in court—94% in fact—has also roped in an accessory.

We are increasingly pursuing a broader range of accessories, including accountants and human resources managers."

Section 550 allows the FWO to seek to recoup back payments and penalties from:

- *the beneficiaries of the labour accountable for exploitation of their contractors' and subcontractors' workers; and*
- *individuals involved in the breach irrespective of whether the corporate employer is still operative, or has money in the bank.*

Up until recently, directors were pursued as accessories, however, they now include human resources staff, admin managers, staff in recruitment and supervision, other companies involved in the supply chain. The FWO will look at the serious and deliberate nature of the conduct involved – lawyers and accountants can also be implicated for advice provided in regards to such arrangements and production of false records.

A range of orders, in addition to penalties and orders for payment by individuals can be sought including:

- injunctions against future contraventions;
- freezing orders to prevent the shifting or assets; and
- orders to compel employers and individuals to commission audits of their entire payroll and training in respect to workplace obligations.

Failure to heed these warnings and turning a blind eye to outsourced work that is performed by another enterprise using contractors on below-award rates of pay may expose organisations and individuals up the procurement chain to significant liability and risks.

Therefore, the outsourcing relationship must be pro-actively and appropriately developed by:

- evaluating whether outsourcing is a viable strategy for the organisation given goals and objectives;
- analysing and assessing information on services outsourced and service deliverables;
- selecting the appropriate vendor including:
  - examining the business operations proposed by the contractor;
  - assessing whether the contractor will be able to deliver the services on the terms proposed and in a manner consistent with the FWA;
  - imposing appropriate controls over further delegation, or subcontracting any of the serviced to be performed; and
  - taking appropriate warranties from service providers in relation to their industrial compliance;
- securing a contract that protects the organisation yet is flexible enough to accommodate unplanned events;
- developing a transition plan for transferring outsourced activities to the vendor;
- establishing and executing an effective governance structure and embarking on appropriate audit activity, supported by relevant contractual rights.; and
- developing guidelines for reappointment of the subcontractor. ■

MEET THE TEAM

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Nic has over 10 years of experience as a commercial lawyer with experience in major transactions, private public partnerships, mergers and acquisitions and providing complex regulatory advice. He was previously in house legal counsel at Macquarie University (including Macquarie University Hospital) where he worked on the development of major assets. He provides advice for hospital operators, universities, aged care providers, private health insurers and medical device companies.

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