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Contents

Introduction 2
New Governance Standards for Charities 3
HEALTH
Prescription and Administration of Drugs to Mentally Ill Patients – What are the consent issues? 5
National Safety and Quality Health Service Standards – Do they apply to you? 7
Euthanasia: An Australian and International Perspective 9
Liability for Volunteers and Good Samaritans 11
LIFE SCIENCES
$3 Billion Fine for Health Care Infringement: The Case of GlaxoSmithKline 13
mHealth – Mobile Medical Apps – When are they medical devices? 14
MEDICO-LEGAL
High Court Confirms that Doctors are not Liable for a Failure to Warn Risks that do not Eventuate – *Wallace v Kam* 15
A Second Bite of the Medical Negligence Apple The Wrongful Birth Decision of *Waller v James* 16
Can Insurers be in Breach of Discrimination Laws by Setting Premiums? *Dulhunty v Guild* Insurance Ltd 17
Trespass to the Person – The Decision of *Dean v Phung* 19
RETIREMENT LIVING AND AGED CARE
Living Longer, Living Better Reforms 20
GENERAL
Privacy Law Reform and Health Information 22
Employment Law Update – Employer Liability for Sexual Harassment 25
Social Media and the Health Practitioner Regulation National Law 26
PROFILED LAWYERS

Introduction

Welcome to the May 2013 edition of the Holman Webb Health Law Bulletin.

The last six months have seen significant development with the introduction of the National Safety and Quality Health Service Standards, not-for-profit governance standards and aged care reform, all of relevance to the sector. The High Court recently delivered its decision in *Wallace v Kam*, confirming that a medical practitioner is not liable for a failure to warn of a risk that did not eventuate.

We are pleased to announce that Holman Webb has been appointed to the Commonwealth Legal Services Multi-use List for government and administrative law and corporate and commercial law. This appointment is of strategic importance to our health, aged care and life science practice.

Our health, aged care and life science team continues to grow with Sandra Ivanovic, Senior Associate, joining us from the NSW Ministry of Health.

The health, aged care/retirement living and life science sectors form an important and growing part of the Australian economy, 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, in both the "for profit" and the "not-for-profit" sector. ■

Health, aged care and life sciences team

New Governance Standards for Charities

by Alison Choy Flannigan, Partner and Joann Yap, Graduate

The Australian Charities and Not-for-Profits Commission (**"ACNC"**) commenced operation on 3 December 2012, with the automatic registration of all charities that were previously approved for charity tax concessions by the Australian Taxation Office. New charities may voluntarily apply to be registered with the ACNC. Registration is a prerequisite for eligibility for certain benefits, including charity tax concessions.

The *Australian Charities and Not-for-Profits Commission Act 2012 (Cth)* ("**ACNC** Act") lists a number of requirements necessary for registration. Following registration, charities must:

- comply with governance standards;
- comply with applicable external conduct standards;
- maintain required records;
- report annual information statements to the ACNC; and
- notify the ACNC of certain changes to the charity's details.

Governance standards

Registered charities are required to meet governance standards. The following five governance standards are set out in the *Australian Charities and Not-for-Profits Commission Amendment Regulation 2013 (No 1)*:

- **Purposes and not-for-profit nature of a registered entity:** Charities must be not-for-profit and work towards their charitable purposes. They must be able to demonstrate this to the ACNC and provide information about their purpose to the public.
- **Accountability to members:** Charities must take reasonable steps to be accountable to their members and provide their members adequate opportunity to raise concerns about how the charity is governed.
- **Compliance with Australian laws:** A charity must not commit a serious offence (such as fraud) under any Australian law or breach a law that may result in a penalty of 60 penalty units ($10,200) or more.
- **Suitability of responsible entities:** Charities must check that their responsible persons are not disqualified from managing a corporation (under the Corporations Act 2001 (Cth)) or currently disqualified from being a responsible person for a registered charity by the ACNC Commissioner and charities must take reasonable steps to remove responsible persons who do not meet these requirements.
- **Duties of responsible entities:** Charities must take reasonable steps to ensure that the members of their governing body know and understand their legal duties and carry out their duties.

The above minimum governance standards for registered charities apply from 1 July 2013, however. transitional provisions apply for certain incorporated associations until 1 July 2017[1].

[1] *Australian Charities and Not-for-profits Commission Amendment Regulation* 2013 (No 1), Subdivision 45-D

External conduct standards

Charities that send funds or engage in activities outside Australia must also meet external conduct standards which are aimed at maintaining public confidence that registered charities manage their affairs openly, use resources efficiently, manage risks and pursue their purposes. It is proposed that these standards will be made and enacted by 1 July 2013.

Records

Financial and operational records must be maintained by registered charities for accessibility or production upon the ACNC's request. Financial records record the charity's transactions, financial position and performance and allow financial reports to be prepared and audited. Operational records will depend on the charity's size and will likely include governing rules, operational policies and procedures and minutes of meetings.

Reporting

Registered charities must provide two types of reports to the ACNC:

- annual financial statements; and
- an annual information report.

The ACNC Commissioner also has the power to request additional reporting from a charity in certain situations.

Registered charities have to report annual information to the ACNC:

- for all charities (small, medium and large) – annual information statements (AISs) from the 2013 reporting period onwards. The 2013 AIS will not include financial information but in 2014 and future years the AIS will include financial information.
- for medium and large charities – annual financial reports from the 2014 reporting period onwards. Small charities can provide the reports voluntarily if they wish and all charities have the option of voluntarily providing them in 2013.
- charities that are basic religious charities do not have to provide annual financial reports and do not have to answer financial questions in the 2014 AIS and future AISs.

For the financial 1 July 2013 to June 2013 and onwards, all registered charities must submit their AIS within 6 months of the end of the charity's reporting period.

Notifications

Registered charities must notify the ACNC if certain changes occur, including to the:

- charity's name;
- address for service;
- responsible persons;
- governing rules; and
- any significant contravention of the ACNC Act or significant non-compliance with the governance or external conduct standards which results in the registered entity no longer being entitled to be a registered charity.

References: "Reporting – what do I need to report?" www.acnc.gov.au; *Australian charities and Not-for-Profit Commission (Consequential and Transitional Act 2012 (Cth).* ■

Prescription and Administration of Drugs to Mentally Ill Patients – What are the consent issues?

by Alison Choy Flannigan, Partner

A story broadcast on the 29 August 2012 segment of the ABC Lateline Program has placed the prescription of anti-psychotic drugs to the elderly and mentally disabled without adequate consent in the spotlight.[2] In that case, the subject of a coronial inquest, it was alleged that an elderly patient with dementia died following administration of anti-psychotic drugs and a morphine injection her daughter and medical guardian (who was a registered nurse) had refused consent to. More broadly, issues have been highlighted concerning the obligations on health and aged care providers in the administration of drugs to patients who are incapable of providing consent.

Health and aged care providers must obtain the consent of a patient (or their substitute decision maker). Failure to obtain consent can give rise to any one or more of the following:

- a cause of action against the health or aged care provider in assault or battery (under the tort of trespass to the person or as a criminal offence);
- a negligence claim; and/or
- a complaint of professional misconduct.

There are limited statutory and common law exceptions such as emergencies. Patients have the right to refuse medical treatment, subject to some statutory and common law exceptions, including in relation to the treatment of children.

The High Court of Australia in Rogers v Whitaker (1992) 175 CLR 479 has held that in providing information to patients for the purposes of obtaining consent there is a duty to warn of a material risk inherent in the proposed treatment. Material risks are those that, in the particular circumstances, would significantly influence the likelihood of a "reasonable person in the patient's position" consenting to the proposed treatment.

Where treatment is reckless or there was an intention to cause death, it may be deemed manslaughter or murder. Inappropriate prescription of drugs can also lead to prosecution under laws regulating therapeutic goods and the Pharmaceutical Benefits Scheme.

Key requirements of consent

The requirements for meeting both the legal and professional practice requirements of consent for treatment are:

- The patient must be legally capable of granting consent. If they are unable to do so, a substitute decision maker must have the legal authority to make the decision on their behalf.
- The patient must give their consent voluntarily, without duress.
- They must be able to understand the nature of the treatment proposed and the advice being given to them.
- The consent must be based on sufficient information about the treatment and its risks and benefits. This information must be appropriate to the circumstances of each patient.
- Consent may be given in writing, orally or by conduct. In most routine examinations and treatment the patient's consent can be obtained verbally. However, where the proposed treatment involves complex or invasive procedures, anaesthesia or sedation, good professional practice warrants the use of a signed written consent form to document the process of consent and confirming the patient's agreement to the proposed treatment.

[2] Lateline, 29 August 2012, 'Doctors could face prison over drug prescriptions, Australian Broadcasting Corporation, http://www.abc.net.au/lateline/content/2012/s3579035.htm

A patient with a mental illness, dementia or other condition or disability potentially affecting their ability to make informed decisions may consent to treatment if the health care provider is satisfied that they are able to understand the proposed treatment, the information provided and the risks and benefits of treatment and the patient is able to indicate their agreement to have the treatment.[3]

If there is doubt about the patient's ability to comprehend and/or make an informed decision, the health care provider should obtain further clinical advice on the patient's capacity and/or seek the consent of a legally authorised substitute decision maker or apply for approval from an appropriate legal tribunal, body or Court.

Restricted or prohibited treatments and involuntary patients

Some special medical treatment specifically requires Court approval, for example the sterilisation of intellectually disabled persons under the *Mental Health Act 2007 (NSW)* and the *Children and Young Persons (Care and Protection) Act 1988 (NSW).*

Under State and Territory Mental Health legislation, special restrictions/rules of consent and approval may also apply in relation to treatments such as prolonged deep sleep therapy, psychosurgery and electroconvulsive therapy.

Under section 85 of the *Mental Health Act 2007 (NSW)* a medical practitioner must not, in relation to any mental illness or mental condition or suspected mental illness or mental condition, administer, or cause to be administered to a person a drug or drugs in a dosage that, having regard to professional standards, is excessive or inappropriate. Section 86 requires mental health facilities and community services to have systems to review drug.

Enduring powers of attorney

A general power of attorney is a mechanism for giving an agent authority to manage a person's financial and property affairs. It does not give the person appointed power to make health treatment decisions on behalf of a patient.

However, an enduring power of attorney, created under relevant State or Territory laws, enables the nominated person, as the attorney for the patient, to make health treatment decisions for the patient when the patient becomes incapable of doing so themselves.

Advance care directives

A person may make an "advance care directive": a statement that the person does not wish to receive medical treatment, or medical treatment of specified kinds. If an advance care directive is made by a capable adult, is clear and unambiguous, and extends to the situation at hand, it must be respected. It would be a battery to administer medical treatment to a person of a kind prohibited by the advance care directive. There may be a qualification if the treatment is necessary to save the life of a viable unborn child.[4]

Guardians or persons responsible

In order to allow for necessary treatment to proceed for adult patients unable to make decisions themselves, there is legislation in place in all jurisdictions to allow for substituted consent by a hierarchy of decision makers:

(i) *Medical Treatment Act (Health Directions) Act 2006 (ACT);*

(ii) *Powers of Attorney Act 2006 (ACT);*

(iii) *Guardianship Act 1987 (NSW)*

(iv) *Adult Guardianship Act 1988 (NT);*

(v) *Powers of Attorney Act 1998 (QLD);*

(vi) *Consent to Medical Treatment and Palliative Care Act 1995 (SA);*

(vii) *Guardianship and Administration Act 1993 (SA);*

(viii) *Guardianship and Administration Act 1995 (TAS);*

(ix) *Medical Treatment Act 1988 (VIC); and*

(x) *Guardianship and Administration Act 1990 (WA)* ■

[3] Re C (adult: refusal of medical treatment) [1994] 1 All ER 819.

[4] Hunter and New England Area Health Service v A [2009] NSWSC 761

HEALTH

National Safety and Quality Health Service Standards – Do they apply to you?

by Alison Choy Flannigan, Partner

Under the National Health Reform Agreement, the Commonwealth and all States and Territories of Australia have agreed to the Australian Commission on Safety and Quality in Health Care (Commission) developing national clinical standards.

The National Safety and Quality Health Service Standards **(NSQHS Standards)** developed by the Commission were introduced on 1 January 2013.

The Commission itself is not a regulator[5] and therefore the implementation and regulation of compliance with the NSQHS Standards is through a number of laws and government policies.

The current NSQHS Standards centre on 10 major areas:

1. Governance for Safety and Quality in Health Service Organisations;
2. Partnering with Consumers;
3. Preventing and Controlling Healthcare Associated Infections;
4. Medication Safety;
5. Patient Identification and Procedure Matching;
6. Clinical Handover;
7. Blood and Blood Products;
8. Preventing and Managing Pressure Injuries;
9. Recognising and Responding to Clinical Deterioration in Acute Health Care; and
10. Preventing Falls and Harm from Falls.

Public health facilities and services

Under the National Health Reform Agreement, States and Territories have agreed to adopt the standards throughout Australian public hospitals.[6] Various State and Territory Health Departments are implementing policies to adopt the NSQHS Standards.

The Commission has stated that the NSQHS Standards also apply to public dental clinics and oral health services.

Private health facilities and day procedure centres

Under the *Private Health Insurance Act 2007 (Commonwealth)*, registered private health insurers must have "complying health insurance products" in order for those policies to attract government support, including Medicare rebates and lifetime health cover.

A complying health insurance policy under that Act meets the quality assurance requirements if the policy prohibits the payment of benefits for a treatment that does not meet the standards in the *Private Health Insurance (Accreditation) Rules 2011 (Cth).*[7]

The Private Health Insurance (Accreditation) Rules 2011 will progressively adopt the NSQHS Standards from 1 January 2013.[8]

Therefore, from 1 January 2013 relevant services funded by a registered private health insurer may be required meet the NSQHS Standards.

[5] National Health Reform Agreement, clause B83

[6] National Health Reform Agreement, Schedule D, section D5(d).
[7] *Private Health Insurance Act 2007 (Cth)*, sections 63-10 and 81-1.
[8] *Private Health Insurance (Accreditation) Amendment Rules 2012* (No 2).

Accreditation cycles; interim arrangements; core and development actions; and applicable and non-applicable actions

The accreditation cycles remain unchanged. After 1 January 2013 the next scheduled recertification audit or organisation-wide accreditation visit will involve assessment against all 10 NSQHS Standards.

For a mid-cycle assessment period review or surveillance audit scheduled anytime after 1 January 2013, a mid-cycle assessment will involve, at a minimum:

- Standards 1, 2 and 3;
- the organisational quality improvement plan (or equivalent); and
- recommendations from previous accreditation assessments.

The Commission has published some minimum requirements[9] to satisfactorily meet some stated core actions in 2013. These requirements will only apply during 2013.

Each of the NSQHS have core (mandatory) requirements and development actions.

Each Standard also has applicable and non-applicable actions depending upon the type of health service organisation and service. Therefore, organisations must read the NSQHS Standards carefully for applicability.

Interim accrediting of new health service organisations

New health service organisations will not necessarily be able to meet all 236 actions in the 10 Standards and, therefore, a number of actions have been prescribed as minimum requirements or are not applicable for the initial 12 months of operation.

Private Dental Services

For private dental services, the accreditation process will largely be established as a voluntary, self-regulated scheme supported by industry through the Australian Dental Association. ■

[9] Australian Commission on Quality and Safety in Health Care - NSQHS Standards, *Minimum requirements for 2013*, 24 September 2012, http://www.safetyandquality.gov.au/wp-content/uploads/2012/09/Minimum-requirements-for-2013.pdf (8 February 2013).

Euthanasia: An Australian and International Perspective

by Sarah Perkins, Special Counsel

In mid-August 2012, Merin Nielsen was released from a Queensland prison after serving six months of a three year jail sentence for assisting the suicide of 76 year old Frank Ward in 2009. He is the only person ever to be convicted in Queensland of the offence.

In the same week, the British High Court of Justice refused the petition of Tony Nicklinson and another man, known by the pseudonym Martin, to legally allow a doctor to assist each man to commit suicide: *(Nicklinson, R (on the application of) v Ministry for Justice* [2012] EWHC 2381). Just six days later Mr Nicklinson died, apparently of "natural causes" although there were some media reports that he had refused nutrition from the time he was informed of the Court's decision. Martin's fate and his identity, remain unknown.

In South Australia, the day before Mr Nicklinson died, Joanne Dunn asked doctors to withdraw artificial nutrition from her son, Mark Leigep. Mr Leigep had been in a coma since March 2006 after suffering severe head injuries in a motor vehicle accident. Although Ms Dunn felt that her son died in 2006, she intended to sit with his body for as long as it takes for him to "starve to death". She has been told it may take two weeks or even longer. She felt she ought to have the right to gather her son's family and friends and together say goodbye as he is "put to sleep".

It was precisely this distinction between the theoretically passive cessation of treatment and the active steps necessary to end life that was raised before the British Law Lords. It was common ground that the applicants were competent adults and, as such, entitled to refuse treatment, including artificial nutrition.

This position had been affirmed in Australia by the Supreme Court of Western Australia *(Brightwater Care Group (Inc) v Rossiter* [2009] WASC 229). In that case Mr Rossiter, a quadriplegic for over 20 years, had instructed his carers at the Brightwater facility to cease to provide artificial nutrition and hydration. Brightwater was concerned that if staff complied with that direction, an offence might be committed, especially in relation to the provisions of the Western Australian Criminal Code that related to the provision of the necessities of life to those in one's charge. The Court was very clear. Firstly, it affirmed that, as a competent adult capable of communicating his wishes, Mr Rossiter had the right to refuse treatment. Accordingly, the Court did not consider that he was in the charge of Brightwater, despite the fact that, in a physical sense, he was dependent on it. The Court ordered that further medical information be provided to Mr Rossiter regarding the likely consequences for him if nutrition and hydration were withdrawn and that, following the provision of that information, Mr Rossiter repeated his directive, it was to be followed.

Five weeks later Mr Rossiter died from a chest infection after refusing antibiotics.

Mr Nicklinson and Martin were aware of their respective right to refuse nutrition. However, each of them felt that the pain and distress associated with that course of action made it unpalatable. Martin sought clarification from the Department of Public Prosecutions as to the likelihood of a prosecution being launched against a person who assisted him in travelling to Zurich to avail himself of the euthanasia services provided by Dignitas. Mr Nicklison, unable to travel to Zurich due to the severity of his condition, sought a declaration that it would not be unlawful, on the grounds of necessity, for a doctor to terminate or assist in terminating his life and further, or in the alternative, a declaration that the current law in relation to murder and assisted suicide is incompatible with Mr Nicklinson's right to respect for private life under Article 8 of the European Convention.

Whilst the Court sympathised with each man, it ultimately refused to grant either the relief sought. The Court held that any attempt by the DPP to clarify whether a hypothetical prosecution would be launched was constitutionally improper as it would usurp the position of Parliament and undermine the "blanket ban" on assisted suicide currently imposed.

The Court refused to allow a doctor to end Mr Nicklinson's life on the grounds that this would be a fundamental change of the long established law of murder, that the defence of necessity simply could not be stretched to cover this situation and that any such radical change ought to be made by Parliament.

Turning to the final issue of the European Convention, the Court concluded that, in relation to the law of assisted suicide, member states had "a wide margin of application" and it was a matter for Parliament.

Few will argue that the British Law Lords were wrong at law. Whether one believes passionately in the inherent sanctity of human life or in the inviolable right of an individual to self determination, it seems clear that any change in the existing law is for Parliament to decide, not the Courts.

HEALTH

However, in mid June 2012 in a judgment spanning some 395 pages, the Supreme Court of British Columbia held that the Canadian Charter of Rights and Freedoms invalidated those provisions of the Criminal Code of Canada which prohibit physician assisted dying: Carter v Canada (Attorney General) 2012 BCSC 886.

The reasons for the judgment can be summarized thus:

- even the very best palliative care cannot alleviate all suffering, except possibly through sedation to the point of persistent unconsciousness;
- it is lawful for physicians to withdraw or withhold life sustaining measures with appropriate consent and further, accepted practices allow the administration of medications even in doses which may hasten death;
- medical practitioners disagree about the ethics of physician assisted death;
- public opinion is divided on physician assisted death;
- the most commonly expressed reason for disallowing physician assisted death is that no system of safeguards will protect vulnerable people, however this is not borne out in those few jurisdictions where it is permitted;
- the law does not prohibit suicide, however those persons physically disabled such that they cannot commit suicide without assistance are denied that option due to the prohibition on assisting suicide;
- that distinction is discriminatory as it is based on physical disability and it perpetuates disadvantage;
- there is a less drastic means available to achieve the aim of protection of vulnerable persons (ie: instead of a complete prohibition in assisting suicide, a stringently limited, carefully monitored system of exceptions allowing grievously and irremediably ill adult persons who are competent, fully informed, non ambivalent and free from coercion and duress to access physician assisted suicide) therefore the legislation does not impair equality rights as little as possible; and
- accordingly, the absolute prohibition on assisted suicide is not constitutional.

Indeed, the Court held that, in respect of at least one of the plaintiffs, the legislation affected her right to life because her evidence was that if she was not able to avail herself of physician assisted suicide, she would need to take her own life while she was still physically able to do so.

The Court suspended the declaration of invalidity for one year to allow the legislature to take steps to amend the legislation. However, one of the plaintiffs was granted a constitutional exemption during the period of the suspension and specifically permitted to seek and proceed with physician assisted death under specified conditions.

In mid-January 2013 international media reported that Belgian doctors had euthanized Marc and Eddy Verbessem, 45 year old identical twins, deaf since birth and losing their sight. Despite neither man having a terminal illness, doctors were satisfied that once deprived of their sight the twins would be suffering unbearable psychological suffering and ought to be allowed to access physician assisted suicide.

Given the absence of an Australian Bill of Rights, Australian Courts will continue to consider this a matter for the legislature. In light of our aging population and the ability of modern medicine to sustain life, at least in terms of quantity if not quality, society will need to carefully consider what our law ought to be in this regard. ■

Liability for Volunteers and Good Samaritans

by Alison Choy Flannigan, Partner

Volunteers

In Australia, there is State and Territory legislation which provides limited protection for volunteer members of community organisations.[10] Whilst based upon the same model there are differences between jurisdictions. This article focuses on the position in New South Wales.

Under Part 9 of the *Civil Liability Act 2002 (NSW)* **(Civil Liability Act)** four broad criteria must be met before a volunteer may take advantage of the protection. A "volunteer" must:

- be working on a "voluntary basis";
- be performing "community work" that is "organised" by a "community organisation";
- be within an area of liability protected by the Act; and
- not fall within a stated exception.

"Community organisation" means any body corporate (such as an incorporated association or company), church or other religious organisation, or authority of the State, that organises community work by volunteers and that is capable of being sued for damages in civil proceedings.

"Community work" means work that is not for private financial gain and which is done for a charitable, benevolent, philanthropic, sporting, educational or cultural purpose, but does not include work declared by the regulations not to be community work.[11]

A "volunteer" means a person who does community work on a voluntary basis.

"Work" includes any activity. However, community work done by a person under an order of a Court is not to be regarded as work done on a voluntary basis. Community work for which a person receives remuneration by way of reimbursement of reasonable expenses in doing the work, or within limits prescribed by the regulations, is to be regarded as work done on a voluntary basis.

A volunteer does not incur any personal civil liability in respect of any act or omission done or made by the volunteer in good faith when doing community work that is organised by a community organisation or as an office holder of a community organisation.

There are various limitations on the protection.

[10] See New South Wales *(Civil Liability Act 2002), Victoria (Wrongs Act 1958, ss 37-41)*, Queensland *(Civil Liability Act 2003, ss 38-44)*, Western Australia *(Volunteers and Food and Other Donors (Protection from Liability) Act 2002)*, South Australia *(Volunteers Protection Act 2001)*, ACT *(Civil Law (Wrongs) Act 2002)*, Northern Territory *(Personal Injuries (Liabilities and Damages) Act 2003)*, Tasmania *(Civil Liability Act 2002)*.

[11] *Civil Liability Act* 2002 (NSW) s 60 (1).

The immunity only applies when the volunteer is acting within the scope of activities authorised by the organisation and is following relevant instructions.[12] Protection from liability is also excluded when the volunteer was engaged in conduct that constitutes a criminal offence,[13] the volunteer was intoxicated[14] or engaged in activities for which insurance was is required by law.[15] Liability is also excluded for motor accidents in which the volunteer is engaged, that would have been covered by a third-party insurance policy or would have been recoverable from the nominal defendant.[16]

The Civil Liability Act is exceptional in protecting the community organisation or other body that utilises volunteers[17] from vicarious liability for the actions of its volunteers. Other Australian jurisdictions have enacted provisions that transfer to the organisation the liability that would have been incurred by the volunteer.[18] However, the New South Wales legislation should be read in conjunction with the *Law Reform (Vicarious Liability) Act 1983 (NSW).*[19]

Further, there may be some Commonwealth Laws that may take priority to the extent of any inconsistency between the Commonwealth and State Laws, for example liabilities under the *Corporations Act 2001 (Cth).*

Good Samaritans

Section 57 of the Civil Liability Act (NSW) also provides some protection for "Good Samaritans" in respect of any act or omission done or made by the Good Samaritan in an emergency when assisting a person who is apparently injured or at risk of being injured. A Good Samaritan is a person who, in good faith and without expectation of payment or other reward, comes to the assistance of a person who is apparently injured or at risk of being injured. The section does not affect the vicarious liability of any other person for the acts or omissions of the good Samaritans.

The protection from personal liability does not apply if it is the Good Samaritan's intentional or negligent act or omission that caused the injury or risk of injury in respect of which the Good Samaritan first comes to the assistance of the person.

Further, the protection from personal liability does not apply if:

(a) the ability of the Good Samaritan to exercise reasonable care and skill was significantly impaired by reason of the Good Samaritan being under the influence of alcohol or a drug voluntarily consumed (whether or not it was consumed for medication); and

(b) the Good Samaritan failed to exercise reasonable care and skill in connection with the act or omission;[20] or

(c) a person is impersonating a health care or emergency services worker or a police officer or is otherwise falsely representing that the person has skills or experience in connection with the rendering of emergency assistance.[21]

Commentary

All health care facilities and community organisations should procure and maintain appropriate insurance, including directors and officers, professional indemnity, public liability and workers compensation insurance to cover their officers, employees and agents (including volunteers). However, it is useful to be aware of these limited protections. ■

[12] Ibid s 64.
[13] Ibid s 62.
[14] Ibid s 63.
[15] Ibid s 65.
[16] Ibid s 66.
[17] Ibid *Civil Liability Act 2002 (NSW)*, s 3C
[18] See for example ACT *(Civil Law (Wrongs) Act 2002)* s 9, Victoria *(Wrongs Act 1958)* s 61
[19] *Law Reform (Vicarious Liability) Act 1983 (NSW)* s 10.

[20] Civil Liability Act 2002 (NSW), s 58
[21] Ibid.

$3 Billion Fine for Health Care Infringement: The Case of GlaxoSmithKline

by Alison Choy Flannigan, Partner
and Joann Yap, Graduate

In July 2012, the global health care conglomerate GlaxoSmithKline LLC (**GSK**) pleaded guilty and agreed to pay $3 billion to the United States Government to resolve its criminal and civil liability stemming from the company's unlawful promotion of prescription drugs for uses that were not approved by the United States Food and Drug Administration (**FDA**), failure to report required safety data, using gifts to encourage doctors to prescribe the drugs, and civil liability arising due to alleged false price reporting practices. This settlement is the largest in United States history for alleged healthcare fraud.[22]

The drug **Paxil** was alleged to have been unlawfully promoted by GSK for treating depression in patients under the age of 18, even though the antidepressant was never approved or tested by the FDA for use by anyone under 18 years old. The United States Government contended that GSK took part in preparing, publishing and distributing a medical journal article that was misleading in that it reported that a clinical trial of the drug was effective in treating depression in patients under the age of 18, when the study in fact failed to demonstrate efficacy.

In relation to the drug **Wellbutrin**, it was alleged that GSK promoted the drug for the treatment of weight loss, sexual dysfunction, abuse addictions, Attention deficit hyperactivity disorder, and other off-label uses, even though the drug was only approved at the time for major depressive disorder. GSK agreed to plead guilty to misbranding the drug as its labelling was inadequate in providing directions for the off-label uses.

It was also alleged by the United States Government that GSK had failed to include certain safety data about the diabetes drug **Avandia** in its reports to the FDA, including information on post-marketing studies and studies undertaken in response to concerns raised by European regulators about the drug's cardiovascular safety.

Amongst other allegations, it was also submitted that GSK paid kickbacks to physicians and other health care professionals to induce them to promote and prescribe various drugs, the flow-on effect caused false claims to be made to federal health care programs.

GlaxoSmithKline will be subject to more stringent requirements under its corporate integrity agreement with the Office of the Inspector-General of the US Department of Health and Human Services, which is designed to increase accountability and transparency and prevent future fraud and abuse. ■

[22] US Department of Justice – Press release "GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data" Monday July 2 2012.

mHealth – Mobile Medical Apps – When are they medical devices?

by Alison Choy Flannigan, Partner

The US and Australia are experiencing the proliferation of mobile medical apps (software applications that can be executed on a mobile platform), which seek to provide a number of functionalities, many of which operate between traditional disease management and health and wellness. Some of these new apps assist consumers with their health and wellness management, whilst others provide healthcare providers with tools to improve and facilitate the delivery of patient care.

United States

The US Food and Drug Administration (**FDA**) released "*Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications*" (**Draft US Guidance**) in July 2011, which has recently been the subject of US Government inquiry and review. The Draft US Guidance explains how the FDA intends to regulate select software applications intended for use on mobile platforms.

The FDA defines a "mobile medical app" as a mobile app that meets the definition of "device" in section 201(h) of the *Federal Food, Drug, and Cosmetic Act* (**FD&C Act**) and includes an application that:

(a) is used as an accessory to regulated medical device, for example a remote display to a medical monitor; or

(b) transforms a mobile platform into a regulated medical device, for example an attachment to a blood glucose strip.

The FDA will apply regulatory oversight in respect of applications which allow the user to input patient-specific information and, using patient-specific formulae or algorithms, output a patient-specific result, diagnosis or treatment recommendation to be used in clinical practice or to aid in making clinical decisions.

The US Guidance does not consider the following as medical apps:

Mobile apps containing only medical reference materials which do not contain patient specific information:

- Mobile apps which are solely used to log, record, track, evaluate or make decisions or suggestions related to developing or maintaining general health and wellness;
- Medical apps which are generic aids for example a magnifying glass; and
- Mobile apps that perform the functionality of an electronic health record system.

Manufacturers of mobile medical devices are subject to the requirements described in the applicable device classification regulations.

Australia

The Australian Therapeutic Goods Administration (TGA) regulates the quality, safety and performance of medical devices and uses a regulatory framework that includes software for therapeutic purposes, which falls under the definition of a "therapeutic good" under the *Therapeutic Goods Act 1989 (Cth)* (**Act**).

In Australia, whether a mobile health and medical app is a "medical device" and/or a "therapeutic good" (and regulated as such) depends principally upon:

1. functionality; and
2. the claims made in relation to the product.

Therapeutic goods includes goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for "therapeutic use" (as defined) and includes medical devices, subject to stated exceptions.

Section 41BD of the Act states that

(1) A medical device includes:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or ….

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a).

The Medical Technology Association of Australia (MTAA) in its submission on "*Apps Purchases by Australian Consumers on Mobile and Handheld Devices*" dated January 2013 recommended the "regulation of smartphone medical apps that are intended by the developer to cure, treat, monitor or diagnose a medical condition."

In that paper the MTAA mentions that the TGA has stated that it will regulate health apps for smartphones as the need arises. ■

High Court Confirms that Doctors are not Liable for a Failure to Warn Risks that do not Eventuate – *Wallace v Kam*

by Zara Officer, Special Counsel

In the recent decision of *Wallace v Kam* [2013] HCA 19 (8 May 2013) the High Court agreed with the NSW Court of Appeal that a medical practitioner is not liable to pay compensation for injuries which occur during surgery for failing to warn of a risk that did not materialise.

Mr Wallace sought treatment of a longstanding condition in his lumbar spine. Dr Kam, neurosurgeon, performed the surgery. The procedure had inherent risks. One risk was temporary local nerve damage, "bilateral femoral neuropraxia", resulting from lying face down on the operating table for an extended period. Another distinct risk was a 1 in 20 chance of permanent paralysis resulting from damage to the spinal nerves. Mr Wallace was not warned of either of these risks. The surgery was performed with all due skill but it was unsuccessful. Mr Wallace suffered bilateral femoral neuropraxia which caused him significant pain for a period of time, but which eventually resolved. Had Mr Wallace been warned of the risk of bilateral femoral neuropraxia he would have proceeded with the surgery. The risk of paralysis did not materialise.

The High Court unanimously agreed that Dr Kam was not liable for the complication suffered by Mr Wallace as a result of the surgery, because Mr Wallace would have accepted the risk of bilateral femoral neuropraxia and would have gone ahead and had the surgery even if he had been warned about that complication. It was not legally relevant that Mr Wallace would not have had the surgery at all if he had been warned of the risk of paralysis. Because Mr Wallace was prepared to accept the risk of temporary local nerve damage, the High Court held that he should not be compensated when it arose.

The underlying policy of the duty to warn is the patient's right to choose. If the patient is prepared to hazard the risk of a certain complication, and the complication arises, then according to the High Court's ruling the practitioner is not liable.

Practitioners should continue to be diligent about warning patients of relevant and significant risks of treatment, because they will be liable for risks that eventuate that are not warned, and are not acceptable to the patient. However, a practitioner will not be held liable for injuries that are sustained during treatment, when they have failed to warn of other distinct risks that did not materialise. ■

MEDICO-LEGAL

A Second Bite of the Medical Negligence Apple – The Wrongful Birth Decision of *Waller v James*

by John Van de Poll, Partner
and Vahini Chetty, Lawyer

The New South Wales Supreme Court has recently handed down the decision of *Waller v James [2013] NSW 497*. Keeden Waller was born on 10 August 2000. On 14/15 August he suffered an extensive stroke, as a result of which he will be disabled for the rest of his life.

Keeden was conceived by invitro fertilisation (IVF). His father, Lawrence Waller, suffers from an anti-thrombin deficiency (AT3) which can result in deep vein thrombosis (DVT) and pulmonary embolism (PE). Mr Waller himself had experienced periods of hospitalisation due to DVT. It was found at birth that Keeden had inherited his father's AT3 .

Deborah Waller, Keeden's mother, launched a wrongful life case on Keeden's behalf which was pursued all the way to the High Court of Australia in 2006.[23] Wrongful life cases are brought by children who owe their very existence to an act of medical negligence. These cases are brought against the medical practitioner against which negligence is alleged. The position in Australia with respect to wrongful life cases has traditionally been that owing to the sanctity of life, it cannot be said that someone's very life or existence is something which should give rise to damages. The decision reached by the High Court in this instance was no exception. The High Court ultimately found by majority that "*Keeden's life with disabilities is not legally cognisable damage in the sense required to found a duty of care towards him*".[24] The appeal was accordingly dismissed.

Following this, the Wallers brought an action for wrongful birth in the Supreme Court of New South Wales.[25] Wrongful birth actions are brought by the parents of children who were generally unplanned and who are born following an act of medical negligence.

At the time that proceedings were commenced, the Wallers alleged that Keeden had suffered a stroke as a result of the AT3. They claimed damages for their involvement in the IVF procedure and the pregnancy as well as damages for psychiatric and physical injury arising from Keeden's disabilities and the cost of raising and caring for him.

[23] See *Waller v James; Waller v Hoolahan [2006] HCA 16.*
[24] *Ibid*, per Crennan J at 86
[25] See *Waller v James [2013] NSWSC 497*

The Wallers alleged that Dr James, the gynaecologist from whom they had received the IVF treatment which resulted in Keeden's birth was negligent in that he had failed to advise them as to the potential inheritability of AT3 and that he had failed to properly refer them to a genetic counsellor or raise with them the possibility of conception via donor sperm. It was the Waller's contention that if they had been informed that AT3 could be passed on to their children, they may have waited a few years until a test was available which could have detected AT3 prior to the birth of a child. Alternatively, they stated that they may have considered using donor sperm.

Justice Hislop found that Dr James did not owe a duty to inform the Wallers of the availability of donor sperm as there was little support for this among the experts.[26]

It was established that Dr James had handed the Wallers a post-it note with the details of a genetic counsellor contained on it and asked that they phone her.[27] However, the Wallers contended that Dr James had never explained the purpose of the post-it note to them and that they were simply told "Ring that lady about that". Dr James did not make a note of this referral and never followed it up. Hislop J found that Dr James should have explained to the Wallers why they were required to call the genetic counsellor, that he should have made a record of the referral in his progress notes and that he should subsequently have followed it up. That the part of the allegation was therefore found to have been established.[28]

The allegation that Dr James breached his duty of care to inform the Wallers as to the inheritability of AT3 was also found to be established.[29]

Ultimately however, the case turned on causation, that is, whether it could be established that Keeden's stroke was materially contributed to by the AT3.

Accordingly, Hislop J ultimately found that the Wallers had failed to establish liability on the part of Dr James. The appeal was dismissed and the Wallers were ordered to pay Dr James' costs of the proceedings.[30] ■

[26] *Supra* 3 at 93-100
[27] *Supra* 3 at 51-57
[28] *Supra* 3 at 90-92
[29] *Ibid*
[30] *Supra* 3 at 269 and 351

Can Insurers be in Breach of Discrimination Laws by Setting Premiums? *Dulhunty v Guild Insurance Ltd*

by Sarah Perkins, Special Counsel

The issue of whether or not an insurer may discriminate in relation to medical indemnity premiums was canvassed in the decision of *Dulhunty v Guild Insurance Ltd [2012] VCAT 165*. It is a condition of registration with the Chiropractic Board of Australia that professional indemnity insurance be maintained. In order to fulfill his insurance obligations, Mr Dulhunty (a chiropractor) maintained insurance provided by Guild Insurance Ltd (Guild). He was not a member of the Chiropractors' Association of Australia (**CAA**), nor was he required to be a member of that body.

It came to Mr Dulhunty's attention that Guild charged him a higher premium than that charged to members of the CAA. He complained to the Victorian Equal Opportunity and Human Rights Commission on 1 December 2010 on the basis that the CAA is an industrial organization and therefore being a member of the CAA, or not, is an industrial activity. He contended that Guild was in breach of the Equal Opportunity Act 1995 (Vic) (**the Act**) as it was discriminating against him on the basis of industrial activity.

Mr Dulhunty sought an order requiring Guild to cease its practice of charging different premiums depending on CAA membership and sought reimbursement of the difference in premiums paid by him from 1998 to 2006 and from 2008 to the present.

Guild conceded that they had discriminated against Mr Dulhunty on the basis of industrial activity, but argued that the discrimination was lawful because it fell within the scope of two specific exceptions.

The first exception relates to discrimination authorized by other legislation (section 69(1) of the Act) and the second relates to the terms of insurance policies (section 43 of the Act, set out below):

Section 43 of the Act states that:

"(1) An insurer may discriminate against another person… in the terms on which an insurance policy is provided, if –

a) the discrimination is permitted under the Sex Discrimination Act 1984 or the Disability Discrimination Act 1992 of the Commonwealth; or

b) the discrimination is based on –

i) actuarial or statistical data on which it is reasonable for the insurer to rely; or

ii) if there is no such data, on other data on which it is reasonable to rely –

and is reasonable having regard to that data and any other relevant factors; or

c) if neither of the above paragraphs applies, the discrimination is reasonable having regard to any relevant factors."

Guild further argued that even if Mr Dulhunty was successful, VCAT could only make an order regarding the premiums charged to him personally, not chiropractors as a group and that reimbursement of premiums ought to be restricted to the 6 year period prior to his complaint (as opposed to the 12 years sought).

The legislation Guild relied upon as authorizing the discrimination was Commonwealth legislation. VCAT held that the exception contained within s69(1) of the Act referred only to Victorian legislation and subordinate instruments.

VCAT also held that Guild could not rely on section 43 of the Act (set out above). Guild argued that being a member of a professional association lowered an insured's risk profile as that association provided information and strategies for risk management, education and training, as well as the opportunity of sharing of information. The Tribunal held that Guild failed to consider the information and strategies available or required of chiropractors generally, including those who are not members of the CAA, and the effect on risk profile and that it also failed to consider Mr Dulhunty's individual circumstances in determining his specific risk profile. In doing so VCAT took into account correspondence between Guild and Mr Dulhunty in which he had set out factors that he considered relevant to the risk profile of non-members of the CAA.

MEDICO-LEGAL

Lastly, the Tribunal accepted that it could not make an order requiring Guild to cease charging increased premiums to all chiropractors who are not members of the CAA. This is because the Tribunal cannot make orders extending to persons who are not parties to the proceeding. The Tribunal confined its order to requiring that Guild reassess the premium payable by Mr Dulhunty, given his particular risk profile and taking all other relevant factors into account from the renewal date most proximate to his clear indication that he considered Guild's policy regarding membership of the CAA to be discriminatory.

It seems likely that many professional bodies will fall within the Victorian definition of an industrial organization. Indeed, Guild conceded that membership, or not, of the CAA constituted industrial activity. While many health professionals would not consider that membership of their professional association was industrial activity, it is likely that, at least in Victoria, this is the case. It is hard to see why, for example, the Australian College of Remote and Rural Medicine would not be an industrial organisation for the purposes of the Victorian Act. Certainly, there is nothing to suggest that this is limited to allied health professionals.

Of course, different regimes apply in the different States of Australia. Queensland's anti-discrimination legislation refers to "trade union activity"[31] and Victorian legislation refers to "industrial activity", [32] while New South Wales appears not to recognise any such grounds for discrimination.

However, it is important that insurers carefully consider the grounds upon which premiums are calculated as the duty of utmost good faith set out in section 13 of the *Insurance Contracts Act 1984 (Cth)* will apply.

While the assumption that membership of a professional body infers a particular degree of professional qualifications or experience, this may not be the case. For example, a surgeon who is a member of the Australian Society of Plastic Surgeons hold vastly different qualifications from a doctor who is a member of the American Academy of Cosmetic Surgery. While a professional body may provide education, training and risk management strategies, it may be the case that non-members access those services elsewhere, either voluntarily or because of mandatory requirements of registration with the relevant Board.

Naturally, the ideal basis for premium decisions is actuarial or statistical data. If Guild had been able to establish with historical data that CAA members were involved in significantly fewer claims than non-CAA members, it would have been more difficult for the Tribunal to find in favour of Mr Dulhunty. Having said that, it appears that the Tribunal felt strongly that Guild failed to consider the submissions made to it by Mr Dulhunty in which he listed various factors that, in his view, lowered his personal risk profile.

Of course, the reality is that premiums are ordinarily set using broad generic markers rather than on a case-by-case basis. If those markers are set after careful deliberation and the reasons for their significance documented, then in most cases disputes will not arise. However, if an insured provides information that leads the insurer to believe that that particular individual has a risk profile lower, or higher, than his, or her, peers, that ought to be taken into account when setting premiums for that individual. ■

[31] *Anti-Discrimination Act 1991* (Qld), section 7.
[32] *Equal Opportunity Act 2010* (Vic), sections 4 and 6.

Trespass to the Person – The Decision of *Dean v Phung*

by Bruce Cussen, Partner and
Vahini Chetty, Lawyer

In July 2012, the NSW Court of Appeal in the case if *Dean v Phung* [2011] NSWSC 653 made an award against a dentist in the amount of $1.743 million dollars, after it was found that the Defendant carried out work that was objectively unnecessary and had no therapeutic effect.

This decision is of significance as claims of this nature almost always fall under the Civil Liability Act 2002 (NSW) (**CLA**) which prevents a Court from awarding exemplary or punitive damages .[33]

The rationale in relation to exemplary damages is that they are seen to be punitive in nature, and accordingly it would not be fitting to apply them to causative actions where the unintentional act or omission that caused the injury or death was negligence. Remove: that were intentional, such as negligence..

The facts of the case are as follows: Mr Dean, the Plaintiff, was a trainee arborist at the time of the accident. On 19 December 2001, he was operating a chipping machine into which he was feeding debris. A log pushed back from the chipping machine and struck him under the chin. In the days following the accident, Mr Dean started to experience severe pain in his teeth.

Mr Dean's supervisor arranged for him to consult Dr Phung, the Defendant. Mr Dean consulted with Mr Phung on 52 occasions during the period 15 January 2002 to 6 February 2003 with a further consultation on 18 July 2003. During the period of treatment, Mr Phung carried out root canal therapy and placed crowns on each of the Plaintiff's 28 teeth. Mr Phung bridged the teeth in groups of 2 and 3.[34]

In order for trespass to the person to apply, the action would have to come within section 3B(1)(a) exception of the Civil Liability Act which provides an exception for the award of personal injury damages. The relevant provision states:

> "The provisions of this Act do not apply to or in respect of civil liability (and awards of damages in those proceedings) as follows:
>
> (a) civil liability of a person in respect of an intentional act that is done by the person with intent to cause injury or death... "

[33] s21 *Civil Liability Act* 2002 NSW
[34] Dean v Phung [2011] NSW SC 653, at 4

Accordingly, where it could be said that the personal injury flowed from an act which was intentional rather than negligent, the CLA would not apply in the award of damages.

At first instance, Hislop J of the Supreme Court of NSW found that the treatment rendered was admittedly incompetent, however, His Honor found that it had not been established that it was dishonest and fraudulent. Accordingly, His Honor found that the matter did not come within the section 3B(1)(a) exception of the CLA. As a consequence, no exemplary damages were awarded in the matter.

Mr Dean appealed this finding in the NSW Court of Appeal.

Trespass to the person is an infringement of a person's rights in relation to his or her body by direct interference of another without lawful justification. In order to determine whether there was a cause of action in trespass to person, the NSW Court of Appeal considered whether or Dr Phung had the intent to cause injury.[35] Basten JA elucidated the position that a medical procedure will generally be an intentional act, but that the critical issue was whether, in the particular circumstances, it was done with intent to cause injury.

Expert opinions provided during the course of the proceedings in this case were to the effect that the treatment was unnecessary and that a second or specialist opinion should have been sought before any of the treatment was carried out. In addition, it was found that the treatment rendered was not properly executed and had to be re-performed.

The NSW Court of Appeal found that since the treatment was unnecessary to the Plaintiff's condition, there was no valid consent and the treatment constituted a trespass to the person.

The Court held that Dr Phung had been unjustly enriched during the period of treatment and accordingly awarded an amount for exemplary damages in the sum of $150,000.

In legal circles, there has been great debate about this decision.

There is concern that in permitting an action for trespass to the person the floodgates may be opened in terms of actions that can be brought against medical practitioners.

It is, however, unlikely that this will be the case. The outcome of the decision of the NSW Court of Appeal is dependent on the particular circumstances of this case.

In order for an action in trespass to person to succeed, the Plaintiff must prove that there was an intent to cause harm. Most medical treatment is carried out with the intention of assisting the patient. In this case the treatment was not only unnecessary, it was also poorly executed. Accordingly, it is likely that this cause of action will still be difficult to prove and will be available for genuine claimants in instances of unnecessary treatment. ■

[35] Dean v Phung (2012) NSWCA 223, 26 to 30

AGED CARE & RETIREMENT LIVING

Living Longer, Living Better Reforms

by Sandra Ivanovic, Senior Associate and
Joann Yap, Graduate

The Australian Government has introduced five new Bills that comprise its Living Longer Living Better aged care reform package, which, if passed, will considerably affect the way aged care providers operate. The Australian Government will allocate $3.7 billion over five years, as part of a wide-ranging ten-year strategy to improve aged care and provide more choice, flexibility and easier access to our aging population.

Aged Care (Living Longer Living Better) Bill 2013

The Aged Care (Living Longer Living Better) Bill 2013 (Cth) amends the Aged Care Act 1997 (Cth) and provides four broad categories of change relating to:

- better access to residential care, including the way Government subsidies and resident fees are calculated and the options available to care recipients to pay for their accommodation;
- home care - recognising the growing demand for homecare, the reforms focus on encouraging people to stay at home longer by increasing the number and type of homecare packages available. For example, home care packages will be increased from approximately 60,0000 to nearly 100,000 over the next 5 years;
- governance and administration such as the establishment of the Aged Care Pricing Commissioner and the new Australian Aged Care Quality Agency; and
- minor, administrative and consequential amendments.

From 1 July 2013:

- a new type of care, home care, will replace community care, with four levels of home care packages;
- it will be a condition of all new home care packages allocated to providers that care offered to recipients will be provided on a Consumer Directed Care basis (from July 2015, all home care packages will be required to be delivered this way); and
- an additional dementia supplement and new veterans mental health supplement will be paid to approved homecare providers who care for eligible care recipients, with a similar supplement proposed to be paid to providers of residential care.

From 1 July 2014 each of the following will be introduced:

- The distinction between low and high level residential care will be removed.
- Care recipients will be able to purchase additional amenities or supplementary care services from their residential care provider.
- There will be a new combined income and assets test, and new annual and lifetime caps on means tested care fees for care recipients who enter residential care on, or after, 1 July 2014. The proposed caps for residential care will be $25,000 (indexed) per annum or $60,000 (indexed) in a lifetime. No such changes are proposed for the treatment of the family home.
- All care recipients who can afford to contribute to their accommodation costs will have the choice of paying for their accommodation through a fully refundable lump sum, a rental style periodic payment, or a combination of both. Importantly, care providers will not be able to distinguish between care recipients on the basis of how they choose to pay due to a 21 day period, which allows the care recipients to decide on the type of payment;
- People who entered residential care from 1 July 2014 will continue under their current arrangements, unless they leave care for more than 28 days (and subsequently re-enter care) or they move services and elect to have the new rules apply to them.
- New income testing arrangements will also be introduced for homecare to enable recipients to pay what they can afford with the family home not included in the income test. Depending on the income of the recipient, the annual cap for home care will be $5,000 (indexed) or $10,000 (indexed) . The lifetime cap will be $60,000 (indexed). The income tested fees will not apply to full rate pensioners or those who procured home care prior to 1 July 2014.

Governance:

- Two agencies have been established to support the implementation of the reforms - the Aged Care Reform Implementation Council and the Aged Care Financing Authority.
- It is proposed that from January 2014, an Aged Care Pricing Commissioner will make decisions where required on pricing issues, such as accommodation payments and extra service fees.

The *Aged Care (Transitional Provisions) Act* 1997 will preserve fees, subsidies and payment arrangements for existing aged care recipients who entered care before 1 July 2014.

Australian Aged Care Quality Agency Bill 2013

The *Australian Aged Care Quality Agency Bill 2013 (Cth)* establishes a new Australian Aged Care Quality Agency (**AACQA**) which from 1 January 2014 will replace the existing Aged Care Standards and Accreditation Agency (Accreditation Agency) without impacting on ongoing accreditation processes. The AACQA will have the primary responsibility for monitoring aged care services against quality standards, with functions relating to residential aged care services commencing from 1 January 2014 and functions relating to home care services from 1 July 2014.

The AACQA will effectively retain, the same functions as the Accreditation Agency with further responsibility for quality assurance for home care from 1 July 2014. The accreditation standards will continue to be dealt with in Principles.

The Bill further describes:

- the functions of the CEO of AACQA and its advisory body, the Aged Care Quality Agency Council;
- the appointment processes for the CEO and Council; and
- operational matters relating to AACQA including staffing and reporting.

Although not described in the Bill, the intention is to fund the AACQA through an appropriation from Parliament. The AACQA will also be able to charge for certain services, such as:

- approved providers of residential aged care to be assessed for accreditation or re-accreditation; and
- fees payable by quality assessors for registration, re-registration and professional development fees for education, training services and publications.

Australian Aged Care Quality Agency (Transitional Provisions) Bill 2013

Under the Australian Aged Care Quality Agency (Transitional Provisions) Bill 2013 (Cth) facilitates the transition of the Accreditation Agency's existing assets and liabilities to AACQA.

Aged Care (Bond Security) Amendment Bill 2013 *and Aged Care (Bond Security) Levy Amendment Bill* 2013

Under the Aged Care (Bond Security) Amendment Bill 2013 (Cth) and the Aged Care (Bond Security) Levy Amendment Bill 2013 (Cth), the following new types of lump sum accommodation payments will be introduced:

- Refundable accommodation deposits; and
- Refundable accommodation contributions.

The bond security legislation will be amended to extend the current guarantee scheme for accommodation bonds to refundable accommodation deposits and refundable accommodation contributions. In this manner, lump sum payments paid by care recipients to approved providers will be protected regardless of whether the payment occurred before or after that date.

Sources:

- Implementing the Living Longer Living Better aged care reform package, Overview of proposed changes to the Aged Care Act 1997, November 2012, Australian Government, Department of Health and Ageing.
- Update on the proposed changes to the Aged Care Act 1997 and related legislation, Video Presentation, 2 April 2013, Rachel Balmanno, Assistant Secretary for the aged care reform Transition Branch in the Ageing and Aged Care Division of the Department of Health and Ageing.
- Aged Care (Bond Security) Amendment Bill 2012 Second Reading Speech 13 March 2013, Mark Butler MP House of Representatives.
- Aged Care (Living Longer Living Better) Bill 2013. ■

GENERAL

Privacy Law Reform and Health Information

by Alison Choy Flannigan, Partner

The Privacy Act 1988 (Commonwealth) (**Privacy Act**), which applies to Commonwealth and ACT government agencies and private sector organisations, has been recently amended by the Privacy *Amendment (Enhancing Privacy Protection) Act 2012 (Cth)* (**Privacy Amendment Act**).

The Privacy Amendment Act received royal assent on 12th December 2012, however, most of its provisions will not commence for another ten months (March 2014) to enable organisations to transition to the amended privacy laws.

The amendments follow the 2008 recommendations of the Australian Law Reform Commission in its report – "For Your Information – Australian Privacy Law and Practice" and the September 2012 recommendations of the House of Representatives Standing Committee on Social Policy and Legal Affairs.

The amended Privacy Act intends to bring greater clarity and consistency in privacy laws, and more comprehensive privacy protection. The amended Act will continue to operate concurrently with related State and Territory laws.

Australian Privacy Principles

The Privacy Amendment Act replaces the Information Privacy Principles and the National Privacy Principles with the Australian Privacy Principles (**APPs**) which apply to both Commonwealth and ACT agencies and the Australian private sector. In summary they are:

APP 1 – open and transparent management of personal information

APP 2 – anonymity and pseudonymity

APP 3 – collection of solicited personal information

APP 4 – dealing with unsolicited personal information

APP 5 – notification of the collection of personal information

APP 6 – use or disclosure of personal information

APP 7 – direct marketing

APP 8 – cross-border disclosure of personal information

APP 9 – adoption, use or disclosure of government related identifiers

APP 10 – quality of personal information

APP 11 – security of personal information

APP 12 – access to personal information

APP 13 – correction of personal information

Permitted health situations

The Privacy Amendment Act introduces the concept of "permitted health situation" in a new section 16B.

Collection – provision of a health service

A "permitted health situation" exists in relation to the collection by an organisation of health information about an individual if:

(a) the information is necessary to provide a health service to the individual; and

(b) either:

  (i) the collection is required or authorised by or under an Australian law (other than the Privacy Act); or

  (ii) the information is collected in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation.

Collection – research etc.

A "permitted health situation" exists in relation to the collection by an organisation of health information about an individual if:

(a) the collection is necessary for any of the following purposes:

  (i) research relevant to public health or public safety;

  (ii) the compilation or analysis of statistics relevant to public health or public safety;

  (iii) the management, funding or monitoring of a health service; and

(b) that purpose cannot be served by the collection of information about the individual that is de-identified information; and

(c) it is impracticable for the organisation to obtain the individual's consent to the collection; and

(d) any of the following apply:

  (i) the collection is required by or under an Australian law (other than the Privacy Act);

  (ii) the information is collected in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation;

  (iii) he information is collected in accordance with guidelines approved under section 95A of the purposes of this subparagraph.

Use or disclosure – research, etc.

A "permitted health situation" exists in relation to the use or disclosure by an organisation of health information about an individual if:

(a) the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety; and

(b) it is impracticable for the organisation to obtain the individual's consent to the use or disclosure; and

(c) the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes this paragraph; and

(d) in the case of disclosure – the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information.

Use of disclosure – genetic information

A "permitted health situation" exists in relation to the use or disclosure by an organisation of genetic information about an individual (the first individual) if:

(a) the organisation has obtained the information in the course of providing a health service to the first individual; and

(b) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety of another individual who is a genetic relative of the first individual; and

(c) the use or disclosure is conducted in accordance with guidelines approved under section 95AA; and

(d) in the case of disclosure – the recipient of the information is a genetic relative of the first individual.

Disclosure – responsible person for an individual

A "permitted health situation" exists in relation to the disclosure by an organisation of health information about an individual if:

(a) the organisation provides a health service to the individual; and

(b) the recipient of the information is a responsible person for the individual; and

(c) the individual:

  (i) is physically or legally incapable of giving consent to the disclosure; or

  (ii) physically cannot communicate consent to the disclosure; and

(d) another individual (the **carer**) providing the health service for the organisation is satisfied that either:

  (i) the disclosure is necessary to provide appropriate care or treatment to the individual; or

  (ii) the disclosure is made for compassionate reasons; and

(e) the disclosure is not contrary to any wish:

  (i) expressed by the individual before the individual became unable to give or communicate consent; and

  (ii) of which the care is aware, or of which the carer could reasonably be expected to be aware; and

  (f) the disclosure is limited to the extent reasonable and necessary for a purpose mentioned in paragraph (d).

Increase in the powers and functions of the Australian Information Commissioner

The Act clarifies the powers and functions of the Australian Information Commissioner in the development and registration of APP Codes of Practice, and improves the Commissioner's ability to promote compliance with privacy obligations. The Commissioner may now accept written undertakings from organisations that they will take, or refrain from taking, action to ensure compliance with the Privacy Act.

Cross border disclosure of personal information

The amended Privacy Act imposes greater obligations on APP entities who disclose personal information about an individual to an "overseas recipient", being a person who is not in Australia or an external Territory and who is not the entity or the individual. APP entities must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the APPs (other than APP1) in relation to the information (subject to specified exceptions).

Other Changes

There have been other significant changes in relation to credit reporting and direct marketing (which may affect charitable fundraising by hospitals).

Given space restrictions, this article covers only some of the changes and you are encouraged to review the entire legislation and update your privacy policies and manuals for compliance in due course. ■

Employment Law Update - Employer Liability for Sexual Harassment

by Robin Young, Partner and
Nick Read, Senior Associate

The risks associated with sexual harassment in the workplace are well known. Under the *Sex Discrimination Act 1984 (Cth)*, employers have an obligation to ensure that all employees, and those who come in contact with their employees, are not subjected to sexual harassment. Generally, under the Sex Discrimination Act, an employer will be vicariously liable for the conduct of an employee who sexually harasses another employee unless the employer can show that it took "all reasonable steps" to prevent the conduct.

In order to comply with the obligation to take reasonable steps, most employers have developed and implemented an anti-discrimination policy based on the Australian Human Rights and Equal Opportunity Commission's 2004 guidelines. A recent decision of the Federal Court has emphasised the importance of ensuring that anti-discrimination policies are accurate, up–to-date and expressly prohibit sexual harassment.

In the case of *Richardson v Oracle Corporation Australia Pty Ltd* [2013] FCA 102, a consultant manager made several complaints of sexual harassment by a male sales representative. Whilst the manager initially attempted to ignore the conduct, she eventually lodged a complaint with the employer's Human Resources Department. The Human Resources Department investigated and found that some of the manager's complaints were substantiated. As a disciplinary measure, the Human Resources Department issued a final written warning to the sales representative. The manager subsequently brought a claim against the employer, amongst other matters, alleging that the employer was vicariously liable for the sales representative's conduct because it had failed to take all reasonable steps to prevent the conduct.

In deciding that the employer was vicariously liable, the Federal Court closely scrutinised the employer's anti-discrimination policy. The Court found that the policy was inadequate in several respects, but importantly because it failed to expressly refer to the laws prohibiting sexual harassment in Australia or state that sexual harassment was unlawful and prohibited. Accordingly, the Court found that the employer had failed to take all reasonable steps to prevent the harassment and awarded the employee $18,000 in damages.

The Federal Court's decision highlights the importance of implementing accurate and meaningful anti-discrimination polices. Often the lines are blurred between what conduct may or may not be appropriate in the workplace, and a policy should set out with precision the type of conduct that constitutes sexual harassment and explain that such conduct is unlawful with reference to the relevant laws. It is important for employers to keep track of the developments in anti-discrimination laws and ensure that new laws are incorporated into their policy. For example, the Federal Government recently tabled proposed amendments to outlaw discrimination on the basis of sexual orientation, gender identity and intersex status, and should these laws be passed, they should be incorporated into employment policies. Policies should also include provisions on managing complaints, confidentiality, potential outcomes and disciplinary actions.

Whilst anti-discrimination policies are an important protection for employers, the requirement to take all reasonable steps is onerous. It is vital that all employees are inducted into policies and educated about the type of conduct that is unlawful and the ramifications for engaging in such conduct. The requirement to take all reasonable steps to prevent sexual harassment is ongoing and its purpose is to develop and maintain positive workplace cultures that are free from harassment and discrimination. ■

Social Media and the *Health Practitioner Regulation National Law*

by Tal Williams, Partner

One positive aspect of social media is its ability to create a network of families, patients and staff who can provide mutual support and information to each other online. This enables people to distribute inspirational stories and create support networks. Many institutions consider social media a positive influence in this regard and have created their own online communities.

With the rise of interactive websites, corporate Facebook pages and user driven content, health services providers are now having to deal with additional compliance obligations to ensure that they do not breach section 133 of the *Health Practitioner Regulation National Law* (NSW) in relation to their own sites.[36] That section prescribes that a person must not "*advertise a regulated health service, or a business that provides a regulated health service in a way that is false, misleading or deceptive . . . or . . . uses testimonials or purported testimonials about the service or business*".

So what if the online support, or commentary, contributed by a user, takes the form of a recommendation of a particular doctor, surgeon or health service? Does this constitute a testimonial? The short answer is yes, it does. Similarly, a user may post information on a blog or website that could be misleading or deceptive or which may not accurately represent the relevant service offering.

If a hospital or other medical or health service allows blogs on its own website, has a Facebook page or runs a Twitter account, the institution is responsible for the content of their social networking pages even if they are not the party who inserted the relevant information or testimonial. So if a testimonial appears online, the institution with responsibility for running the site (or on whose Facebook page the testimonial appears) will be accountable for it. Once alerted to the comment, obligations immediately arise that, if left unattended, could result in a breach of the law.

Any health service utilising social media must therefore closely monitor all commentary and blogs and promptly take action to remove any potentially offending remarks. The same principle applies if defamatory, racist or other inappropriate contributions are made by users of the site.

There is a public consultation paper issued in April 2013 by the Australian Health Practitioner Regulation Agency, which calls for submissions on, amongst other things, social media regulation in the industry. Submissions are due by close of business on 30 May 2013. ■

[36] See also: *Health Practitioner Regulation National Law (ACT) Act 2010 s. 133; Health Practitioner Regulation (National Uniform Legislation) Act 2010 (NT); Health Practitioner Regulation National Law Act 2009 (Qld) s. 133; Health Practitioner Regulation National Law (South Australia) Act 2010; s. 133; Health Practitioner Regulation National Law (Tasmania) Act 2010 (Tas); Health Practitioner Regulation National Law (Victoria) Act 2009 s. 133 and Health Practitioner Regulation National Law (WA) 2010 s.* 133.

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Prior to joining Holman Webb, Sandra was a senior commercial lawyer with the NSW Ministry of Health where she gained in depth experience and an understanding of the health industry.

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