Holman Webb
Lawyers

Health Law Bulletin

May 2014

Contents

Introduction

Welcome to the May 2014 edition of the Holman Webb Health Law Bulletin.

The amendments to the *Privacy Act 1988 (Cth)* commenced on 12 March 2014, which are applicable to Commonwealth Government agencies and the private health sector. Ignore them at your peril because the penalties for breaches have significantly increased up to $1,700,000 for businesses and $340,000 for individuals.

It has also been a time of change for the not-for-profit sector and charities and there have been some interesting recent medico-legal cases relevant to the extent of the duty to warn of rare risks and the materialisation of inherent risks.

We trust that this edition of the Health Law Bulletin is informative with articles of relevance to you and your team.

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 expert 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.

A number 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. ■

Alison Choy Flannigan
Partner
Health, aged care and life sciences
Holman Webb Lawyers
T: (02) 9390 8338 M: 0411 04 9459
E: alison.choyflannigan@holmanwebb.com.au

Privacy Law Update

by Alison Choy Flannigan, Partner

Australian privacy rights are regulated by Commonwealth State and Territory legislation and the laws protecting confidential information under the common law.

Australian privacy laws govern the collection, use and disclosure of "personal information". Individuals have a right of access and correction of their own personal information. There are also data security, data quality and cross-border transborder data flow requirements.

Under Australian privacy laws:

*"**personal information**" means information or an opinion about an identified individual, or an individual who is reasonably identifiable:*

(a) whether the information or opinion is true or not, and

(b) whether the information or opinion is recorded in a material form or not.

In Australia, health information (such as medical records) are a subset of personal information and attract additional protection and rules. These include:

- use and disclosure is permitted if there is a serious and imminent threat to the health and safety of an individual or the public;
- use and disclosure for health and medical research if certain conditions are met;
- disclosures to individuals who are responsible for the person for compassionate reasons;
- restrictions on access if providing direct access would pose a serious threat to the life or health of any individual;
- the collection of family, social and medical histories; and
- use and disclosure of genetic information to lessen or prevent a serious threat to a genetic relative.

*"**Health information**" means:*

(a) information or an opinion about:

(i) the health or a disability (at any time) of an individual; or

(ii) an individual's expressed wishes about the future provision of health services to him or her; or

(iii) a health service provided, or to be provided, to an individual; that is also personal information; or

(b) other personal information collected to provide, or in providing, a health service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

*"**Health service**" means:*

(a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the person performing it:

(i) to assess, record, maintain or improve the individual's health; or

(ii) to diagnose the individual's illness or disability; or

(iii) to treat the individual's illness or disability or suspected illness or disability; or

(b) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.

The Privacy Act 1988 (Cth) (**Privacy Act**), which applies to Australian Commonwealth 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 was passed by Parliament on 29 November 2012, received the Royal Assent on 12 December 2012 and came into force on 12 March 2014.

The amendments:

- create a single set of Australian Privacy Principles applying to both Commonwealth Government agencies and the private sector. These principles replace the former Information Privacy Principles and National Privacy Principles;
- introduce more comprehensive credit reporting, improved privacy protections and more logical, consistent and simple language;
- strengthen the functions and powers of the Australian Information Commissioner to resolve complaints, use external dispute resolution services, conduct investigations and promote compliance - penalties of up to 2000 penalty units, amounting to $340K for individuals and AUD$1.7 million for body corporates for serious and repeated offences; and
- create new provisions on privacy codes and the credit reporting code, including codes that will be binding on specified agencies and organisations.

Australian Privacy Principles (APP)

The amendments introduce a unified set of Australian Privacy Principles which apply to both Commonwealth government agencies and the Australian private sector, replacing separate public and private sector principles.

The 13 APPs cover the following areas:

- 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; and
- APP 13 – correction of personal information.

For health care providers, in addition to the significantly increased penalties, there are significant amendments in relation to:

- notification of collection;
- direct marketing (for example consumer engagement and fundraising); and
- transborder dataflows.

Permitted health situations

The amendments introduce 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) the 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 or 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).

All Commonwealth and private sector organisations should update their Privacy Policies and Privacy Manuals to comply with the amended privacy legislation.

2014 likely to be another year of significant change for charities

By Dr Tim Smyth, Special Counsel and Joann Yap, Graduate

2013 saw the legislative and regulatory environment for charities significantly changed. 2014 looks like being a repeat, but in the opposite direction. The government has confirmed its intention to abolish the Australian Charities and Not-for-profit Commission (**ACNC**) and to return to the common law definition of charity of the purposes of Commonwealth laws.

Current framework continues for the time being

Readers should note that the ACNC remains in place and continues to have a major regulatory and compliance oversight of the charities and not for profit sector. Charities registered with the ACNC continue to have important compliance and reporting obligations under the ACNC framework. Charities are required to be registered with the ACNC to maintain their tax exemptions and DGR status.

While unlikely to be of material consequence for most charities, it is also important that all charities review their constitutions, functions and activities to ensure that they come within the statutory definition of "charity" for the purposes of Commonwealth law. This is because the new *Charities Act 2013 (Cth)* (**Charities Act**) commenced on 1 January 2014. It appears unlikely that the government will be able to amend or repeal this legislation for some time.

Commonwealth statutory definition of 'charity'

Under the Charities Act, a statutory definition of charity now applies for the purposes of Commonwealth law. To meet the definition, charities must:

- be a not for profit entity;
- have all of its purposes charitable or incidental or ancillary to or in furtherance or in aid of charitable purposes;
- have no 'disqualifying purposes'; and
- not be an individual, political party or government entity.

Charity under common law

The government's intention is to return to the common law approach to determining a charity. This approach dates back to 1601[1]. Common law has established four principal categories – relief of poverty, advancement of education, advancement of religion and 'other purposes' beneficial to the community. This approach has been endorsed by Australian courts and in ATO rulings.

What has the government announced?

On 19 March 2014, the Federal Minister for Social Services, Kevin Andrews, introduced a Bill into Parliament to abolish the ACNC. *The Australian Charities and Not-for-profits Commission (Repeal) (No. 1)* Bill 2014 will not take effect until a later Bill is passed by Parliament and establishes a successor Agency. As outlined in the Minister's speech to the Australian Institute of Company Directors on 29 January 2014[2], the Government intends to return the ACNC's regulatory and compliance functions to the ATO, ASIC and other bodies (as was the case prior to the establishment of the ACNC in December 2012).

The Minister also confirmed the intention to establish a "National Centre for Excellence" early in the next financial year to provide collaborative education, training and development support to charities.

The Centre for Excellence will have a broader ambit extending to clubs and associations with a social welfare role and entities in the arts, environment, medical research, animal welfare and education sectors.

The Minister summarised the functions of the proposed Centre as:

- provide educational and support services to registered charities;
- provide assistance with the registration process of new charities and not-for-profit organisations;
- provide a 'one-stop-shop' for information on the sector;
- advocate on behalf of the sector by representing its interests to government;
- facilitate communication and interactions between the sector and government;
- undertake research on issues of concern to the sector; and
- foster innovation.

[1] The Statute of Charitable Uses of 1601 (Statute of Elizabeth).
[2] The Honourable Kevin Andrews MP, Minister for Social Services, Address to *Australian Institute of Company Directors, NFP Directors* Lunch (29 January 2014): <http://kevinandrews.dss.gov.au/speeches/45> (25 February 2014)..

What are the key messages?

Substantial changes in the regulatory and compliance framework for charities and not for profit organisations with tax exemptions are likely to occur in 2014/15, with the exact nature of the changes unclear ahead of the new Senate composition in July 2014.

Boards, senior management and auditors should have plans in place to keep informed on mooted changes, maintain an up to date reporting and compliance calendar and ensure effective compliance and risk management is in place.

Entities required to be registered with the ACNC must still provide reports to the ACNC. Charities using the standard 1 July to 30 June financial reporting year must have submitted their 2013 Annual Information Statement by 31 March 2014, and charities operating on a calendar year must submit the statement by 30 June 2014. ■

Employees vs Independent Contractors and the Risks of Sham Contracting

By Robin Young and Alison Choy Flannigan

Who is an employee?

An employee performs work under the 'control' of another person in exchange for payment for the services he or she provides.

A contract of employment may be express or implied, oral or in writing, but preferably in writing.

The High Court of Australia in the leading case of *Hollis v Vabu Pty Limited* (2001) 207 CLR 21 adopted a 'multi-facet test'. Indicators of an employment relationship include:

- Control by the employer, for example instruction as to how to carry out duties, uniform and hours of work, etc. – control indicates an employment relationship;
- The expression of the relationship by the parties in writing, such as calling a contract an 'Employment Contract' or a 'Service Agreement' is persuasive but not determinative;
- The Terms of the contract, for example, is paid annual leave provided? – Employment entitlements such as annual leave, long service leave and parental leave are employment entitlements;
- Was the worker in business on his/her own account? Were tax invoices rendered? Did the worker use their own ABN? The worker operating an independent business indicates that the worker is an independent contractor;
- Was the worker required to work exclusively for the organisation? Exclusivity of arrangement indicates an employment relationship;
- Who provided the resources and equipment? An employer usually provides resources and equipment, whereas an independent contractor provides his/her own equipment.

The indicia of employment are not exhaustive and no one factor is necessarily conclusive.

Legal Obligations of the Employment Relationship

A relationship of employment gives rise to several obligations for an employer, including:

- *Industrial Relations Act 1996 (NSW) and Fair Work Act 2009 (Cth)*;
- workers compensation insurance to cover injury to workers;
- compliance with work, health and safety laws;
- long service leave, annual leave and parental leave;
- compliance with unfair, unlawful dismissal and adverse action laws;
- compliance with Federal Modern and State Awards;
- payment PAYE/income tax, payroll tax, fringe benefits and superannuation; and
- compliance with anti-discrimination and anti-bullying laws.

The Independent Contractor Relationship

The independent contractor relationship is governed by the contract between the organisation and the independent contractor and not employment laws.

Independent contractors need to manage their own business and procure their own insurance for their negligence and income protection. They are often distinguishable from employees by the personal risk associated with their activities.

The *Independent Contractors Act 2006 (Cth)* can provide relief for unfair contracts.

Some laws apply to both the employment and independent contract relationship

These include laws relating to:

- work, health and safety;
- anti-discrimination;
- anti-bullying;
- adverse action claims;
- workers compensation (in some cases); and
- superannuation (in some cases).

What is Sham Contracting?

Under the Fair Work Act 2009 (Cth), which applies to the Commonwealth public sector and private sector, and employer must not tell an employee that they are being hired as a contractor if they are really an employee.

An employer is also prohibited from dismissing or threatening to dismiss an employee in order to hire them as an independent contractor doing the same or substantially the same work.

In addition to civil liabilities, penalties for a breach of these obligations are up to $51,000 for a corporation and $10,200 for an individual for knowingly being involved in a contravention.

Organisations must be aware of the difference between an employment relationship and an independent contractor relationship and the risks of sham contracting.

Confidential disclosures during sexual assault and domestic violence counselling - How can we protect them? *Sampson & Hartnett* [2014] FCCA 99

By Alison Choy Flannigan, Partner and Zara Officer, Special Counsel

Healthcare providers have an interest in ensuring that victims of sexual assault and domestic violence can seek medical and counselling services without compromising their health, safety and emotional wellbeing.

In *Sampson* & *Hartnett* a mother brought proceedings in the Federal Circuit Court of Australia seeking to vary parenting orders. As part of those proceedings the father issued a subpoena seeking health and counselling records from the hospital which had provided health services and counselling to the mother. Arising out of some matters disclosed in the counselling, a mandatory notification had been made to the Department of Family and Community Services by a staff member at the hospital. The hospital objected to producing the health service and counselling records, except for the records relating to the mandatory notification, provided that the name of the informant was redacted from the records.

The *Evidence Act 1995 (Cth)* applied to the proceedings.

In New South Wales the *Evidence Act 1995* provides specific protections for confidential communications, creating a form of privilege for such communications. These communications include counselling, where this occurs in a professional capacity, including counselling for domestic violence and sexual assault. There is also a protected confidences privilege under the *Criminal Procedure Act 1986 (NSW)*, relating to confidential sexual assault communications. These privileges do not exist in the Commonwealth *Evidence Act* and family law proceedings are commonly commenced in the Commonwealth jurisdiction.

In *Sampson & Hartnett*, the Court applied the general rule that evidence that is not relevant in a proceeding is not admissible. The Court upheld the hospital's objection to production of the mother's medical records and counselling records, on the basis that they were not relevant to the substantive issues in the (parenting order) proceedings. The sections of the records relating to a mandatory notification which were relevant, were required to be produced, but the name of the informant was redacted in accordance with the confidentiality provisions in the *Children and Young Persons (Care and Protection) Act 1998 (NSW)*. This Act provides for the identity of the person making the report not to be disclosed without the consent of the person making the report, or leave of the Court.

The hospital had objected to the production of the medical and counselling records of the mother on the basis of relevance, and on public policy grounds in that disclosure of professional confidential records may deter future patients of the health service from attending or participating in counselling and other health services, and undermining confidence in the health service.

Confidentiality of itself is not a ground for setting aside a subpoena or for objecting to production of documents. Under the Commonwealth *Evidence Act*, the key issue is that evidence not relevant to proceeding is not admissible[3]. Deeper protections exist under the NSW Acts, which create a specific "protected confidences" privilege.

General guidelines to protect disclosures

Communications made in the course of providing domestic violence and/or sexual assault counselling may be "protected confidences" or "privileged" in certain situations:

(a) SS.23-29A *Children and Young Persons (Care and Protection) Act 1998 (NSW)*;

(b) SS.126A, 126B, 126H *Evidence Act 1995 (NSW)*;

(c) S.295-306 *Criminal Procedure Act 1986 (NSW)*; and

(d) S.135 *Evidence Act 1995 (Cth)*.

This means that they may be protected from disclosure if the hospital/counsellor receives a subpoena from the Court to produce medical records.

[3] *Evidence Act 1995 (Cth)*, section 56.

The following are some general guidelines to assist hospitals/counsellors to protect disclosures made in the course of providing domestic violence and/or sexual assault counselling:

- Refrain from sending unsolicited letters disclosing that domestic violence and/or sexual assault counselling has been provided (other than communications which are required in order to provide health care to the patient). If you are asked to send such a letter, seek legal advice.
- Do not refer to mandatory reports in correspondence.
- Be aware that mandatory reports (and medical records related to the mandatory report) may be disclosed in certain circumstances, for example, in child custody or child welfare cases.
- Do not refer to or disclose the bottom line, conclusions, substance or gist of a privileged communication which you wish to protect. Disclosure can occur even without an express statement. If there is a clear link between the statement regarding the privileged communication and the subsequent action taken as a result of those communications, a waiver will likely occur. For example, if you disclose that you have been counselling a patient and as a result of the counselling a mandatory report has been provided, you risk waiving privilege (protection) of the counselling notes.
- Minimise the circulation of confidential communications within the organisation as this will risk waiver of privilege. The more people who have seen the records, the less likely a court will view them as having the necessary confidentiality to be privileged. Keeping counselling records in a locked or secure system with limited access greatly assists in maintaining the necessary confidentiality.
- A mere reference to the existence of a privileged communication will not usually amount to a waiver of privilege.
- Be aware that the patients/clients themselves, by their own disclosures, may waive privilege. The patient/client should maintain confidentiality if at all possible.

Holman Webb recently acted in the above matter, the decision of which is reported under a pseudonym. ■

The Extent of the Duty of Medical Practitioners to Warn Patients of Rare Risks When Providing Treatment - *Odisho* v *Bonazzi* [2014] VSCA 11

By Colin Hall, Partner

The Supreme Court of Victoria Court of Appeal's decision in *Grazilda Odisho v Marcia Bonazzi* [2014] VSCA 11 was handed down on 18 February 2014. The writer acted for Dr Bonazzi at trial and again before the Court of Appeal.

This article examines the implications of the Court of Appeals' decision in the context of:

- A medical practitioner's duty of care to warn a patient of a rare risk associated with the medical treatment (sections 48, 50, 58 and 60 of the *Wrongs Act 1958 (Vic)*[4]) ; and
- The role of factual causation (sections 51 and 52 of the *Wrongs Act 1958 (Vic)*[5]).

Ms Odisho (the **Appellant**), who at the time of treatment was a 46 year old female sought treatment from Dr Bonazzi, a gynecologist, for menorrhagia. It was accepted evidence that when she presented before Dr Bonazzi she was very anxious. Having regard to her particular circumstances the only available medical treatment for the menorrhagia was tranexamic acid until further investigations could be performed at the Women's Hospital in 3 months' time.

The patient took the tranexamic acid tablets at the recommended dose over a week to two week period and subsequently thereafter developed a pulmonary embolus. The Appellant thereafter commenced proceedings out of the County Court of Victoria alleging that Dr Bonazzi had been negligent in her care of rhe Appellant by failing to warn of the likelihood, however remote, that the ingestion of tranexamic acid could cause pulmonary emboli.

Following *Rogers v Whitaker* (1992) 175 CLR 479 it is well accepted law in Australia that a medical practitioner has an obligation to warn a patient regarding 'material risks'.

[4] *Wrongs Act 1958*, sections 48, 50, 58 and 60.
[5] *Wrongs Act 1958*, sections 51 and 52.

"The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it." (ibid 489-490)

Dr Bonazzi defended the proceeding at trial on two bases:

- that the subjective limb of universally accepted principal of *Rogers v Whitaker* did not require her to give a warning in this instance as the Appellant would not have attached any significance to such a warning given her particular circumstances; and
- there was no available medical literature or factually based evidence that the ingestion of tranexamic acid at the prescribed level could cause a thrombosis. The Appellant's own medical background did not put her into a special class of persons who should have been warned regardless of the absence of any such literature in any event.

At trial Dr Bonazzi gave evidence that when the Appellant was commenced on the treatment there was no definitive link between tranexamic acid and thromboembolism. In fact, Dr Bonazzi was informed by, amongst other things, the MIMS Annual which stated at the time:

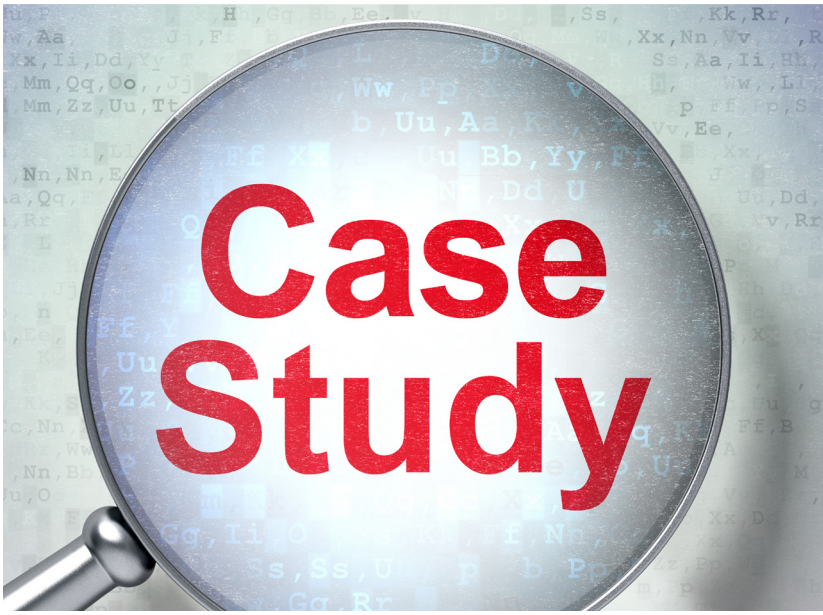
> *"Although clinical evidence shows no significant increase in thrombosis, possible risk of thrombotic complications cannot be ruled out".*

On that basis and having regard to the fact that the Appellant ruled out any other form of treatment given her particular circumstances tranexamic acid was the only available interim treatment.

Expert evidence called was to the following:

- Studies published four years after the commencement of the treatment indicated that the risk of pulmonary embolism was less than one in one thousand.
- Clinical studies also suggested there was at best a temporal connection between tranexamic acid and pulmonary emboli. In one study 10,000 people were given tranexamic acid and 10,000 people were given a placebo. The placebo group recorded a higher degree of vascular occlusions than the group taking tranexamic acid.

Based on this evidence, the Court found that the Appellant could not prove factual causation that the tranexamic acid treatment led to the pulmonary emboli from which she had suffered.



In addition, the Court considered whether the provision of a *Rogers v Whitaker* warning would have affected the Appellant's decision as to whether or not to undergo treatment with tranexamic acid. It was found that tranexamic acid was the least invasive treatment available for the Appellant's heavy bleeding condition and that in all likelihood she would still have undergone the tranexamic treatment if she had been warned of the risk of pulmonary embolism.

In considering Dr Bonazzi's duty to warn the Appellant of the risk, the Court of Appeal did note that despite the low statistical possibility of thrombotic complications, *"that it was at least fairly arguable that Dr Bonazzi was under a duty to warn the Appellant"* but that even had the Appellant been warned of the remote risks she would not have declined the treatment. Hence the trial judge's decision finding in favour of Dr Bonazzi that she did not breached her duty of care by failing to warn the Appellant was upheld by the Court of Appeal.

The Court of Appeal's decision reinforces the need for medical practitioners to be kept well informed and updated with available literature as well as to pay regard to a patient's particular circumstances. If the medical practitioner forms the view that the patient would place significance on a reported risk, even a remote risk, then that information should be provided to the patient prior the treatment being commenced.

Odisho has now applied to the High Court for special leave to appeal the SCCA decision. The application for special leave is being defended. ■

Is a hospital liable for the criminal acts of its mental health patients?

By John Van de Poll, Partner and Vahini Chetty, Solicitor

In the recent case of *McKenna v Hunter & New England Local Health District; Simon v Hunter & New England Local Health District [2013] NSWCA 476*, the New South Wales Court of Appeal held that a hospital and the health district was liable to the family members of a man who was murdered by one of its patients.

Mr Pettigrove suffered from a lengthy history of mental illness including depression, psychosis and chronic paranoid schizophrenia. In the early hours of 20 July 2004, Mr Pettigrove's friend, Mr Rose, became concerned about his mental state and arranged for him to be taken by ambulance to Manning Base Hospital (the Hospital) in New South Wales. The principal cause of Mr Rose's concern was that his friend was experiencing what he described to be "physical jerks".

Upon presenting to the hospital, Mr Pettigrove was assessed and a certificate was issued for his compulsory detention.

Later that day a meeting was held between the duty psychiatrist, Dr Coombes, Mr Pettigrove, Mr Rose and the duty nurse. Mr Pettigrove requested during the course of the meeting that he be permitted to return to his family in Victoria and receive ongoing treatment. Mr Rose indicated that he wished to drive Mr Pettigrove back to his family and it was agreed that he would be permitted to do so the next day.

During the course of that night, Mr Pettigrove was witnessed by nursing staff to have been pacing in his room and talking loudly to himself.

On the morning of 21 July 2004, Dr Coombes once again assessed Mr Pettigrove and noted that he did not have any hallucinations or distressing thoughts. Mr Pettigrove was given enough medication for one day (one Risperidone tablet) and was discharged into Mr Rose's care. Dr Coombes gave evidence that Mr Pettigrove was to share the driving to Victoria and there was a concern that providing him with additional medication would have caused drowsiness.

That evening Mr Pettigrove and Mr Rose stopped near Dubbo after nightfall. It was then that Mr Pettigrove strangled and killed Mr Rose. In an interview with police, Mr Pettigrove stated that he had acted on impulse, believing that Mr Rose had killed him in a past life leading him to seek revenge.

Mr Rose's mother and his two sisters, Ms Simon and Ms McKenna (the Appellants) brought an action against the Hunter & New England Local Health District for psychiatric injury resulting from the nervous shock, claiming that the hospital had breached its duty of care by discharging Mr Pettigrove into Mr Rose's custody.

The majority in this case found that in light of his behavior the night before, his history of mental illness; the fact that it was more likely that Mr Pettigrove would become more agitated at night; the appreciable risk that Mr Pettigrove would suffer an acute psychotic episode of the type that had led to his admission to the hospital; the fact that the oral medication administered on the morning of 20 July 2004 was likely to have been wearing off and the fact that but for Mr Rose's offer to drive Mr Pettigrove he would not have been discharged from the Hospital as he was not fit to travel by public transport, the hospital had breached its duty of care owed to Mr Rose.

The Court also found that the hospital's decision to discharge Mr Pettigrove was a necessary condition of the occurrence of harm to Mr Rose as he was not given further medication as a result of the intended road trip and was effectively under-medicated at the time that he killed Mr Rose. This liability was found to extend to the Hunter & New England Local Health District.

The Appellants were awarded damages and an order for costs was made in their favour.

It is noteworthy in this case that because the hospital discharged Mr Pettigrove directly into Mr Rose's care, a clear link could be found between the hospital's decision to discharge Mr Pettigrove and the resultant harm. In contrast, in the case of *Hunter Area Health Service v Presland* [2005] NSWCA 33, it was found that the hospital in question was not liable where a psychiatric patient killed his brother's fiancé six hours after being discharged. The Court found in that case that once the hospital's control was lost by the refusal to detain the patient, it was difficult to see how a duty for control extended for some indeterminate period while the patient was at large. This case was however distinguished from the present decision on its facts. ■

Update on National Board Requirements: Revised Guidelines, Codes of Conduct and Policies for Registered Health Practitioners

By Alison Choy Flannigan, Partner and Joann Yap, Graduate

The National Boards regulating registered health practitioners in Australia have released revised guidelines, codes of conduct and a new social media policy, which came into effect from 17 March 2014. Registered health practitioners should review these documents to ensure their practice meets National Board expectations from that date, including the:

- revised *Guidelines for Advertising Regulated Health Services*;
- revised *Guidelines for Mandatory Notifications*;
- revised *Code of Conduct*; and
- new *Social Media Policy*.

The National Boards will refer to the new documents in relation to conduct occurring after 17 March 2014.

Guidelines for mandatory notifications

The Guidelines for mandatory notifications describe the mandatory notification requirements under the National Law[6]. Although some wording has been refined or added for clarification, most of the guidelines have not changed and no new obligations have been added.

Amendments clarify the following:

- mandatory notification is not required if a practitioners' behaviour is being appropriately managed through treatment and does not pose a risk to the public;
- individuals who are not subject to mandatory notification obligations (such as patients) can make voluntary notifications;
- the person with most direct knowledge about notifiable conduct should generally be encouraged to make a notification themselves;
- for practitioners reporting notifiable conduct, a 'reasonable belief' must be formed in the course of practising the profession. The following principles are drawn from legal cases which have considered the meaning of reasonable belief:

- a belief is a state of mind;
- a reasonable belief is a belief based on reasonable grounds;
- a belief is based on reasonable grounds when all known considerations relevant to the information of a belief are taken into account including matters of opinion and those known considerations are objectively assessed; and
- a just and fair judgement that reasonable grounds exist in support of a belief can be made when all known considerations are taken into account and objectively assessed; and
- the requirement to make a mandatory notification is triggered by a practitioner practising their profession while intoxicated by alcohol or drugs.

New exceptions have been created for practitioners in Western Australia and Queensland in certain circumstances:

- treating practitioners in WA are not required to make mandatory notification when their reasonable belief in misconduct or impairment is formed in the course of providing health services to a health practitioner or student; and
- following the commencement of the *Health Ombudsman Act 2013 (Qld)*, practitioners in Queensland are not required to make a mandatory notification when their reasonable belief is formed as a result of providing a health service to a health practitioner, where the practitioner providing the service reasonably believes that the notifiable conduct relates to an impairment which will not place the public at substantial risk of harm and is not professional misconduct. In Queensland, mandatory notifications must be made to the Health Ombudsman, rather than AHPRA, however the Ombudsman must advise AHPRA about the notification in certain circumstances.

[6] *Health Practitioner Regulation National Law (NSW)*, Part 8, Division 2 (and similar legislation in other States and Territories).

Code of Conduct

All National Boards publish a Code of Conduct – the National Medical Board and Nursing and Midwifery Board publish their own profession-specific codes.

The Code of Conduct contains a number of important standards in relation to:

- providing good patient care, including shared decision-making;
- working with patients or clients;
- working with other healthcare practitioners;
- working within the healthcare system;
- minimising risk;
- maintaining professional performance;
- professional behaviour and ethical conduct;
- ensuring practitioner health;
- teaching, supervising and assessing; and
- undertaking research.

Amendments include:

- clarification that the Code applies to the practitioners conduct regardless of the setting, including for social media, e-health and technology-based patient consultations;
- good practice also includes being aware that differences such as gender, sexuality, age, belief systems and other anti-discrimination grounds in relevant legislation may influence care needs, and avoiding discrimination on the basis of these differences;
- effective communication in all forms underpins every aspect of good practice;
- good care includes facilitating the quality use of therapeutic products based on the best available evidence and the patient or client's needs;
- encouraging patients or clients to communicate other health advice they have received, including prescriptions or other medications they have been prescribed and any other therapies they are using;
- ensuring social media use and e-health is consistent with the practitioner's ethical and legal obligations to protect patient privacy;
- being mindful of additional informed consent requirements when supplying or prescribing products not approved or made in Australia;
- good practice involves an awareness of the cultural needs and contexts of all patients and clients, to obtain good health outcomes;
- good practice involves behaving professionally and courteously to colleagues and other practitioners at all times, including when using social media;
- good practice involves supporting students and practitioners receiving supervision within a team; and
- practitioners need to be aware of and comply with any guidelines of their National Board in relation to professional boundaries.

Advertising Guidelines

The advertising guidelines explain the legal requirements about advertising, which are set in the National Law[7] and have been reorganised to make them clearer and provide further clarification and additional explanations, but do not include any new obligations.

Social Media Policy

The new Social media policy explains how the obligations that already exist in the National Law and Code of Conduct apply to social media, but does not change the basic obligations to be met by practitioners. These include the expected standards of professional behaviour, limits on the way in which health services are advertised, and compliance with confidentiality and privacy requirements. The primary principle is that those obligations apply to the behaviour of practitioners whether it occurs online or in person. ■

[7] Section 133 *Health Practitioner Regulation National Law (NSW)* and similar legislation in other States and Territories.

Professional boundaries in Health and Aged Care – where is the line?

By Dr Tim Smyth, Special Counsel

Two decisions in NSW, reinforce the requirement for all registered health professionals to understand and respect professional boundaries with patients. Both cases involved an allied health professional.

In the case before the Physiotherapists Tribunal of NSW, the Tribunal found that a lack of judgement by a physiotherapist allowed a personal and wider family friendship to develop with a patient to an extent that crossed the professional boundary. In the Tribunal's view, this lack of understanding and recognition of professional boundaries amounted to unsatisfactory professional conduct. The Tribunal reprimanded the physiotherapist and imposed conditions, including a requirement for mentorship.

The second case was before the Psychologists Tribunal of NSW. The Tribunal found that the psychologist had failed to maintain proper professional boundaries with his client. The Tribunal held that this conduct amounted to unsatisfactory professional conduct and determined to reprimand the psychologist and place conditions on his registration, including a requirement to undertake further education and to undergo a period of supervised practice. The psychologist was also ordered to pay 90% of the costs of the Health Care Complaints Commission.

These cases remind health professionals of the need to:

- continually consider the nature of their relationship and interaction with their patient or client;
- undertake an appropriate risk assessment, especially if the patient or client is vulnerable, dependent or open to exploitation or the nature of the relationship changes;
- carefully manage involvement of family members with patients and clients;
- be prepared to refer the patient to another practitioner if a material risk of a boundary issue arises; and
- not allow themselves to get into a situation where the relationship raises serious boundary issues or would be perceived by colleagues and the community as being unethical or improper.

HCCC v Shasank Verma [2013] NSWPYT 2 (23 December 2013)

Mr Verma qualified as a physiotherapist in 1993. He first met Patient A in 2001 and provided assessment and physiotherapy services to her as part of his local health service employment. As part of his separate private practice, he also provided services to an aged care facility. Patient A moved into this facility in 2003.

In late 2001 and early 2002, at the patient's initiative, the patient contacted the physiotherapist's wife and a friendship developed, which subsequently extended to the physiotherapist's adolescent children and to Mr Verma. This family friendship included some social activities, birthday gifts, visits to see the patient in the aged care facility and assistance with shopping and transport to appointments. Patient A was a widow and had no close relatives nearby.

Due to concerns she had about how her finances were being managed by others, Patient A subsequently transferred significant sums of money to Mr Verma for safekeeping. On the death of the patient in 2008, Mr Verma received a significant financial benefit under the patient's will.

The Tribunal had difficulty in assessing the HCCC's complaint (which raised 90 allegations) and invited the HCCC to identify the core particulars of the complaint. The Tribunal criticised the Commission for submitting voluminous unnecessary material.

The HCCC asserted that Mr Verma, "allowed and/or encouraged a personal relationship to develop with Patient A". The Tribunal was critical of many of the particulars submitted to the Tribunal by the Commission and did not agree that they demonstrated unsatisfactory professional conduct. The Tribunal also rejected Commission submissions that as Mr Verma's earlier treatment of Patient A was while he was an employee of the local health service, he remained bound by the NSW Ministry of Health's policies and Code of Conduct in his subsequent private physiotherapy services to Patient A.

The practitioner did not dispute many of the factual matters before the Tribunal. The Tribunal accepted that a social relationship with a client and providing compassionate assistance is not unusual, and of itself, would not amount to a failure to maintain proper professional boundaries by a physiotherapist. The Tribunal commented that had the practitioner been a treating psychiatrist for example, the situation would be different.

The Tribunal found that the friendship and support provided to Patient A by Mrs Verma and the children did not attract disapproval of Mr Verma as a physiotherapist.

Patient A repeatedly told her carers, solicitor and GP that she regarded Mr Verma as her next of kin. In 2007, without Mr Verma's knowledge, Patient A changed her will and made Mr Verma her executor and sole beneficiary. Mr Verma did not become aware of this until shortly after Patient A's death.

The Tribunal acknowledged that "elderly patients living in aged care facilities, particularly those with limited contact with family members, will commonly develop a vulnerability to exploitation and abuse by those responsible for their care". The Tribunal found that it was only in the months prior to Patient A's death in November 2008 that she experienced a material decline in her cognitive ability and mental functioning, affecting her ability to make informed decisions about her affairs. The Tribunal did not find that Mr Verma had exploited or abused this vulnerability.

However, the Tribunal did agree that some of Mr Verma's actions ***could have*** resulted in exploitation of Patient A, and that his allowing himself to be placed in such a situation was a breach of the Physiotherapy Registration Board Code of Conduct. The Tribunal found that he should have appreciated and avoided this risk.

The Tribunal had particular concerns in relation to the acceptance by the Vermas of sums of money totalling over $100,000 from Patient A. The Tribunal accepted evidence that Patient A had asked Mrs Verma to hold the money in safekeeping for Patient A, and that Patient A had rejected Mrs Verma's suggestion that the money be deposited into an account opened and controlled by Patient A. The Tribunal noted that the Vermas held a joint bank account and Mr Verma was aware of the deposits.

The Tribunal also had concerns over Mr Verma's agreement in August 2008 to accept appointment as an enduring guardian and a transfer of power of attorney from a relative of Patient A to him. The Tribunal noted that these appointments, and the change in Patient A's will, were overseen by Patient A's solicitor.

The Tribunal found that these two concerns did show a failure to maintain proper professional boundaries and constituted unsatisfactory professional conduct.

A key issue for consideration by the Tribunal was whether the contact between Mr Verma and Patient A between September 2004 and November 2008 constituted physiotherapy assessment and/or treatment. The Tribunal noted that the nature of the treatment was designing exercise programs for Patient A that were implemented by a physiotherapy assistant at the aged care facility. The Tribunal held that this did constitute provision of physiotherapy services by Mr Verma, and hence he continued to have a professional relationship with Patient A.

The Tribunal then considered whether the instances of unsatisfactory professional conduct could also amount to a more serious finding of professional misconduct. While finding that Mr Verma's conduct did demonstrate "a significant lack of judgement and a significant failure on his part to appreciate the necessary professional boundaries that need to be maintained in a proper physiotherapeutic relationship", the Tribunal rejected the Commission's submission that the conduct amounted to professional misconduct. The conduct had not been deliberate, exploitative or an abuse of the relationship with Patient A.

The Tribunal ordered that Mr Verma not provide physiotherapy assessment or treatment to persons aged over 70 years until he completed an ethics course to the satisfaction of the Physiotherapy Council of NSW and he had been mentored for a period of 12 months.

HCCC v Leonard (No 1 and No 2) [2013] NSWPST 4 (7 November 2013) and 5 (20 December 2013)

In this matter, the Commission successfully established its complaints and the Tribunal decided to make a costs order against the psychologist, Mr Leonard. The Commission's complaints were that Mr Leonard:

(a) failed to provide appropriate psychological services to Client A by using telephone coaching and consultations that were not appropriate in her case; and

(b) failed to establish and maintain proper professional boundaries with Client A and failed to adequately respond to an identified boundary issue.

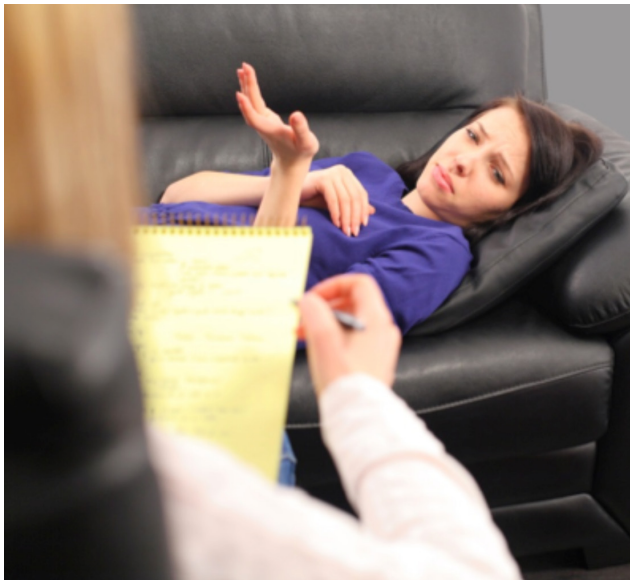
The Tribunal agreed to a request by counsel for Mr Leonard that the matter be considered in two stages – consideration of the complaints and, should the complaints be established, a hearing as to appropriate orders.

Mr Leonard was registered as a psychologist in 1998. He subsequently established a private practice in Sydney and also provided services in regional NSW. In his clinical practice he also utilised telephone counselling.

Client A worked in a medical practice that referred patients to Mr Leonard and they had telephone contact in this context and occasionally saw each other in the street in Chatswood. In 2008, Mr Leonard provided counselling to Client A's child. Client A was referred by her GP to Mr Leonard. Over an 8 month period in 2009, Mr Leonard had face to face sessions with Client A. Subsequently, during a period up until March 2010, they had telephone conversations and communicated by text messages.

Mr Leonard and Client A met three times in December 2009 at a local café and Mr Leonard also sent Client A two photographs of himself. Client A telephoned Mr Leonard in March 2010 to advise him that her husband did not wish her to see him again and she would no longer be in contact with him.

An issue before the Tribunal was whether the conduct of concern occurred during the provision of psychological services and a therapeutic relationship with Client A. Mr Leonard submitted that the therapeutic relationship had concluded at the end of the face to face sessions in August 2009. The Tribunal did not accept this submission and did not find Mr Leonard to be a credible witness. The Tribunal noted that Mr Leonard had made entries in Client A's clinical record in relation to a number of the telephone calls and recorded them as "phone consult/session" or "long phone coach". The Tribunal found that Mr Leonard had continued to provide psychological services to Client A up until March 2010.



In evidence, Mr Leonard acknowledged that Client A was vulnerable and that his role as a psychologist and Client A's trust in him, placed him in a position of power and responsibility. In the Tribunal's expert witness' view, Client A's conduct clearly demonstrated a high level of dependency and a high risk of a transference reaction.

The Tribunal accepted the evidence of an expert psychologist that the multiple attempts by Client A to contact Mr Leonard and the boundary issues associated with telephone contact and SMS messaging should have alerted Mr Leonard to the need to more appropriately manage the situation. The Tribunal noted with concern that many of these calls and messages were after hours, very late at night and on weekends, and that Mr Leonard frequently replied to them.

The Tribunal was satisfied that the continued use of telephone counselling was not appropriate. While a romantic or other relationship between Mr Leonard and Client A was not suggested, Mr Leonard had failed to set clear boundaries with Client A. By continuing to receive and respond to calls and texts from Patient A, Mr Leonard had allowed proper professional boundaries with a vulnerable patient to break down. Much of the telephone contact was of a personal rather than professional nature. The sending of two photos of himself (irrespective of the content) to Client A was unprofessional and a boundary violation, as was his providing counselling to Client A in a social setting at a café. The Tribunal found that Mr. Leonard's conduct "fostered and facilitated the ongoing professional boundary difficulties".

The Tribunal found that in failing to deal with the boundary issues, Mr Leonard demonstrated "either ignorance of his professional ethical obligations or reckless disregard for those responsibilities".

The Tribunal had no difficulty in finding that Mr Leonard's conduct fell significantly below what would be expected from a psychologist with his training and experience and that it was both improper and unethical. This constituted unsatisfactory professional conduct.

The Tribunal then considered whether this conduct was sufficiently serious to warrant a finding of professional misconduct. The common law definition of professional misconduct is that the conduct "would reasonably be regarded as disgraceful or dishonourable"[8] or "such a departure from the accepted standards as would reasonably incur the strong reprobation of professional colleagues of good repute and competence"[9].

Under the National Law governing registration of health professionals, the statutory definition of professional misconduct refers to unsatisfactory professional conduct of a sufficiently serious nature to justify suspension or cancellation of the practitioner's registration.

The Psychology Tribunal has in other cases generally found that a sexual relationship between a psychologist and a client constitutes professional misconduct justifying cancellation of registration.

While expressing concern over Mr. Leonard's conduct and lack of insight, the Tribunal did not believe that his conduct could be equated with other instances where the Tribunal had found the conduct to be the more serious, professional misconduct.

The Tribunal reconvened in December 2013 to consider further evidence and submissions as to the orders the Tribunal should make. The Tribunal found Mr Leonard's conduct to be "a very serious case of unsatisfactory professional conduct, at the high end of the range [of such conduct]".

The Tribunal reprimanded Mr Leonard "in the strongest possible terms", imposed a condition requiring fortnightly supervision for a period of 2 years to "address his failure to appreciate and manage boundary issues" and required him to undertake an ethics course at the St James Ethics Centre. ■

Legal Issues - Collaborations Between Hospitals and Universities and Other Educators

By Alison Choy Flannigan, Partner

Common Arrangements between Hospitals and Universities and other Educational Institutions

There are obvious benefits for hospitals to engage in the training of clinical staff (provided that the training is adequately funded). These include attracting students as future staff of the hospital, attracting quality teaching/specialist clinical talent to the hospital, profiling the hospital in relevant clinical specialities and attracting research funding. For example, the Mayo Clinic in the USA has built its reputation on its academic association[10]. Engaging in workforce development programs for existing staff will also improve staffing qualifications and therefore clinical care as well as enable hospitals to attract and maintain staff with opportunities for progression. Universities have become more dependent upon privately funded international students as a source of income.

The arrangements between hospitals and universities and other educational institutions differ depending upon the type of hospital and the nature of the relationship.

Public hospitals and health services will typically have a long standing arrangement with specific universities, there being in most cases an agreement between the hospital and the university and also a number of State Health Department policies which govern those relationships. These formal arrangements are less likely to be in place with private hospitals and GP clinics.

Common arrangements include:

1. research collaboration, including issues such as funding and contribution, ethics approval, common research strategy, research governance, confidentiality, privacy, intellectual property, commercialisation and publication rights;
2. university academic appointments for university teaching staff at the hospital, including indemnity and insurance;

[8] *NSW Bar Association v Cummins* [2001] NSWCA 284.
[9] *Qidwai v Brown* [1984] 1 NSWLR 100.
[10] Mayo Clinic, http://www.mayoclinic.org/ (7 May 2014).

3. student placement, including the qualifications, selection and conduct of students, supervision, disciplinary issues, compliance with hospital and university policies, patient consent, working with children checks, confidentiality and privacy, immunisation and insurance;
4. arrangements with Registered Training Organisations for vocational training of staff; and
5. accommodation and equipment arrangements, whether they be leases, licences or sessional arrangements to the enable of use of hospitals facilities by academic and other university staff.

Before a hospital engages in the training of students and enables those students to interact with or treat patients, the hospital operator must ensure that adequate arrangements are in place to manage these issues.

Registered Training Organisations (RTOs)

The Australian Government has created a number of funding programs to support national productivity through the development of workforce skills and manages these through Skills Connect.[11]

Hospital operators, as employers may enter into workforce development training arrangements with RTOs which are registered with the Australian Skills Quality Authority (**ASQA**).

The Community Services & Health Industry Skills Council is a broker for workforce development funding,[12] and provides valuable funding for health service employers.

Arrangements between hospitals and RTOs typically include issues such as the description of the workforce development program, training participants, timetables, funding, including compliance with relevant Commonwealth funding conditions (which are generally not-negotiable), confidentiality and privacy, and intellectual property.

Intellectual Property

One particular issue to consider in entering into a relationship between a hospital operator and a university is the creation, ownership, licence and commercialisation of intellectual property rights because students are not usually employees of the hospital operator or the university and the policies of the hospital and university on intellectual property rights created by academics and students are likely to differ.

It is important for the hospital and the university to clearly set out in their agreements arrangements dealing with the ownership of intellectual property rights upon their creation.[13]

[11] 'Skills Connect' http://skillsconnect.gov.au/ (7 May 2014).
[12] 'Community Services and Health Industry Skills Council' www.cshisc.com.au (7 May 2014).
[13] The word limit of this article does not permit me to expand on this issue in this article, however, refer to *University of Western Australia v Gray* (2009) 179 FCR 346.

Audit report puts spotlight on salaried specialist rights of private practice

By Dr Tim Smyth, Special Counsel

The first of two reports, *Right of private practice in Queensland public hospitals*[14] was completed in July 2013. The second, Right of private practice: *Senior medical officer conduct* completed in February 2014, examined compliance with contractual obligations by a sample of staff specialists.

As outlined in the reports, allegations in Queensland media in late 2012 concerning alleged 'rorting' of the right of private practice arrangements, led to the Minister for Health writing to the Auditor-General expressing concerns about the allegations and the oversight, visibility and transparency of the conduct of senior medical officers (**SMOs**). The Auditor-General initiated a performance audit and tabled the first report in Parliament on 11 July 2013.

The performance audit pursued three lines of inquiry to determine if:

- the intended health and financial benefits of the scheme are being realised;
- the scheme is being administered efficiently; and
- practitioners are participating in the scheme with probity and propriety and in full compliance with contractual obligations.

Private practice arrangements for salaried medical specialists working in the public sector health system vary across Australia. Common elements include payments of allowances, tiered drawing rights from private practice revenue and the ability to conduct an 'outside' private practice, all linked to granting the public sector health service the right to bill chargeable patients on behalf of the practitioner. In Queensland, the majority of specialists (86%) participate under Option A and receive a private practice allowance and assign 100% of private practice income to the health service.

The first report found that financially, Queensland Health paid out at least $800M more in allowances and other salary supplementation over the past decade, than the private practice revenue received. Option A was the biggest contributor to this shortfall - $725.69M over the nine years to 30 June 2012.

[14] Report to Parliament 1: 2013-14 available at www.qao.qld.gov.au.

This finding will not be a surprise to many readers of the *Health Law Bulletin* as health service managers and health departments accept the necessity to provide salary supplementation to recruit and retain specialists. In this regard, the Auditor-General did note that there had been an increase of over 1,200 senior medical officers (**SMOs**) since 2003-2004, with the ratio of SMOs per 100,000 people rising from 31.7 to 56.6 over the 7 years.

The first report also found a significant lack of effective oversight by the health department, health services and clinical unit managers, poor administration and documentation, disparate information systems, poor monitoring and clear compliance gaps.

The recent second report focussed on the third line of inquiry, examining rostering, payments and billing practices for what the Auditor-General termed SMOs in the "category of highest risk for improper conduct".

The report found it difficult to wholly substantiate or disprove the allegations due to the lack of effective monitoring, accountability and governance of the arrangements at a health service and clinical unit level.

The report identified many areas of risk, including poor leave records, SMOs being paid rostered overtime while on leave, rostering practices that facilitated private practice, failure to declare private practice income and billing of private patients where no right of private practice had been documented. Allegations of improper billing were substantiated for twelve SMOs in the sample examined.

Legal implications

In addition to potential disciplinary action against some SMOs for breach of contract and misconduct, the two reports also highlight important legal compliance issues relating to:

- taxation legislation (including income tax and GST);
- the *Health Insurance Act 1973 (Cth)* and eligibility of services for Medicare benefits; and
- state health service legislation.

These legal frameworks impose obligations and civil and criminal penalties for breaches on both the medical practitioner and their employing health service.

As noted in this and previous articles in the *Health Law Bulletin*, the national health practitioner registration law also imposes a code of conduct and duties on registered medical practitioners. The Medical Board of Australia and conduct councils and tribunals have found breaches of this code and duties to constitute unsatisfactory or professional misconduct. These findings have also been made against medical managers.

What should readers do?

As recommended by the Queensland Audit Office, health services should closely review their current right of private practice governance arrangements to ensure:

- transparency and clear formal documentation;
- effective accountability and monitoring;
- compliance with the regulatory framework required by each State and Territory health department;
- billing arrangements compliance with the *Health Insurance Act 1973 (Cth)*; and
- compliance with taxation legislation. ■

Security of Tenure, Ageing in Place and Consumer Directed Care – Legal obligations

By Alison Choy Flannigan, Partner and Joann Yap, Graduate

Approved providers of aged care services, both residential aged care services and home care packages are required to comply with statutory obligations under the *Aged Care Act 1997 (Cth)*.

These obligations regulate many activities, including:

- security of tenure;
- ageing in place; and
- consumer directed care.

When approved providers implement these minimum regulatory obligations into their daily operations, it is important to ensure that they also comply with their duty of care to their clients and employees as well as their contractual obligations with clients and/or their legally authorised representatives.

Security of tenure

Approved providers of residential aged care facilities are required under the *User Rights Principles 1997 (Cth)* to provide security of tenure for a care recipient's place in the residential care service.

The approved provider may ask the care recipient to leave the residential care service only in limited circumstances, namely if[15]:

- the residential care service is closing;
- the residential care service no longer provides accommodation and care suitable for the care recipient, having regard to the care recipient's long-term assessed needs, and the approved provider has not agreed to provide care of the kind that the care recipient presently needs;
- the care recipient no longer needs the care provided through the residential care service as assessed by an aged care assessment team (**ACAT**);
- the care recipient has not paid any agreed fee to the approved provider within 42 days after the day when it is payable, for a reason within the care recipient's control;
- the care recipient has intentionally caused serious damage to the residential care service or serious injury to the approved provider (if the approved provider is an individual) or serious injury to an employee of the approved provider, or to another care recipient; or
- the care recipient is away from the residential care service for a continuous period of at least 7 days for a reason other than a reason permitted by the Act or an emergency.

The long-term needs of the care recipient must be assessed by:

- an ACAT; or
- at least 2 medical or other health practitioners who meet the following criteria:
  - one must be independent of the approved provider and the residential care service, and must be chosen by the care recipient or the care recipient's appropriate representative;
  - both must be competent to assess the aged care needs of the care recipient.

The *User Rights Principles* set out a notification procedure to follow with respect to requiring a care recipient to leave residential care services. The approved provider must give at least 14 days' notice including the following information:

- the decision;
- the reasons for the decision;
- when the care recipient is to leave; and
- the care recipient's rights about leaving, including the right of access to:
  - the complaints resolution mechanism
  - independent complaints processes; and
  - one or more representatives of an advocacy service.

The approved provider must not take action to make the care recipient leave, or imply that the care recipient must leave, before suitable alternative accommodation is available that meets the care recipient's assessed long-term needs and is affordable by the care recipient. There may also be a duty of care owed by the approved provider to ensure that this requirement is met.

Some resident agreements may be more generous than the minimum statutory requirements, so it is important to also consider the relevant resident's agreement before taking action. In some cases, the duty of care to a care recipient may require an approved provider to delay the transfer. To the extent of any inconsistency between the statutory requirement and the resident agreement, the statutory requirement prevails.

Ageing in Place

The *User Rights Principles* also restrict moving care recipients within residential care services.

Under Part 2, Division 5 of the *User Rights Principles* a care recipient may be moved to another bed or room in the residential care service only if:

[15] *User Rights Principles 1997 (Cth)*, Part 2, Division 1.

- the move is at the care recipient's request; or
- the care recipient agrees to move after being fully consulted and without being subject to any pressure; or
- the move is necessary on genuine medical grounds as assessed by:
  - an ACAT; or
  - at least 2 medical or other health practitioners who meet the following criteria:
    - one must be independent of the approved provider and the residential care service, and must be chosen by the care recipient or the care recipient's appropriate representative; and
    - both must be competent to assess the aged care needs of the care recipient; or
- the place occupied by the care recipient becomes an extra service place and the care recipient elects not to pay the extra service fee; or
- the move is necessary to carry out repairs or improvements to the premises where the residential care service operates and the care recipient has the right to return to the bed or room, if it continues to exist as a bed or room for care recipients when the repairs or improvements are finished.

Again, with moving a care recipient within an aged care service, the approved provider must take into consideration its duty of care to the care recipient and the relevant resident's agreement.

Consumer directed care

From 1 August 2013 all new home care packages were required to be delivered on a consumer directed care (CDC) basis. From July 2015, all packages will operate on a CDC basis.

The guidelines for CDC are set out in the Home Care Packages Program Guidelines (August 2013).

CDC is a way of delivering community services that allows consumers and their carers to:

- control the type of care accessed, how and when it is delivered as well as who provides that care;
- set goals in relation to remaining independent for as long as possible, remaining healthy, or returning home after a hospital stay;
- determine a preferred level of involvement in managing the package;
- receive ongoing monitoring and formal reviews by providers to ensure the package continues to meet needs; and
- be provided with greater transparency in how the package is funded and how those funds are being spent through the Care Recipient Agreement.[16]

From 1 August 2013, it became mandatory for all new Home Care Packages in operation after that date (including all packages allocated to providers in the 2012-13 Aged Care Approvals Round) to be delivered on a CDC basis. The introduction of CDC in all packages will apply from July 2015, although providers will be able to convert existing packages to a CDC basis earlier than this date.

The Home Care Packages Program, including the CDC arrangements, has been evaluated by KPMG on behalf of the then Department of Health and Ageing to refine the program before the implementation of CDC arrangements across all Home Care Packages in 2015.

Key findings from the evaluation include:[17]

The KPMG report states that several CDC providers had concerns about balancing the consumer choice elements of the CDC with the provider's duty of care. There may be a conflict between the level of consumer choice to expend their funds as they wish, and a provider's responsibility and duty of care to ensure consumers receive adequate support. Some providers had refused consumer or carer requests that CDC funds be used due to a concern that the consumer or carer's request would compromise the consumer's care, for example, reducing the amount of personal care or clinical care a consumer could use;[18]

Approved providers must balance the consumer's choice with their duty of care to the consumer. The Guidelines state that a home care provider may decline a request from a consumer if the proposed service may cause harm or pose a threat to the health and/or safety of the consumer or staff. Where there is a dispute, this should be resolved by discussion and mediation by a mutually acceptable third party, such as the client's health care provider, where possible. Aged Care recipients may make complaints to the service provider and/or the Aged Care Complaints Scheme. Care recipients may also obtain advice and support from advocacy service through the National Aged Care advocacy line.

All approved providers of aged care services must review their resident agreements, policies and procedures and daily practice on a periodic basis to ensure continuing compliance with changing legislative requirements. ■

[16] DPS Guide, Consumer Directed Care (CDC) Packages, <http://www.agedcareguide.com.au/home-community-care-information.asp?c=53&i=30> (3 February 2014).
[17] Australian Government Department of Health and Ageing, 'Evaluation of the consumer-directed care initiative – Final Report', https://www.health.gov.au/internet/main/publishing.nsf/Content/F072F0C75198E936CA257BF0001A35BF/$File/CDC-Eval-Final-Rep.pdf, January 2012 (3 February 2014).
[18] Id, at 116.

Can you register a patent for a method of medical treatment? *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* [2013] HCA 50

By Alison Choy Flannigan, Partner and Joann Yap, Graduate

The majority of the High Court in *Apotex Pty Ltd v Sanofi Aventis Australia Pty Ltd*[19] has held that some methods of medical treatment of the human body are patentable inventions if certain conditions are met, within the meaning of section 18(1) of the *Patents Act 1990 (Cth)*.

Facts

Sanofi-Aventis Deutschland GmbH was the registered owner of Australian Patent No 670491 entitled "Pharmaceutical for the treatment of skin disorders". The patent had a single claim:

> *"A method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of a pharmaceutical composition containing as an active ingredient a compound of the formula I or II".*

The formulae is then set out. A compound of the formula I is Leflunomide.

Australian Patent No 529341 claimed a chemical formula of Leflunomide, a process for its preporation, a composition containing the compound as an active ingredient and a method claim. That patent expired in 2004.

Apotex Pty Ltd (**Apotex**) intended to supply leflunomide in Australia under the its generic trade name 'Apo-Leflunomide' for the treatment of rheumatoid arthritis and psoriatic arthritis and obtained registration on the Australian Register of Therapeutic Goods. Psoriasis is a skin condition. Leflunomide is not used in Australia to treat psoriasis alone. Dermatologists do not prescribe Leflunomide for that purpose. However, Leflunomide is used by rheumatologists to treat rheumatoid arthritis and psoriatic arthritis. Almost every person with psoriatic arthritis has or will develop psoriasis. The evidence established that when this compound is prescribed to treat a patient with psoriatic arthritis, it is usually expected to also prevent or treat the patient's psoriasis, if the person has a concurrent case of psoriasis.

Sanofi-Aventis argued the supply of the product to treat psoriatic arthritis would infringe its patent. Apotex cross-claimed and sought to have the patent revoked on the basis of invalidity because the patent related to a method of medical treatment, or in the alterative that the claim in the patent did not disclose a patentable invention because it was a second or subsequent medical use of a previously known product.

The issue was whether a method of medical treatment is a 'manner of manufacture within the meaning of section 6 of the Statute of Monopolies'.

Sanofi-Aventis relied on section 117 of the Patents Act 1990 (Cth) which states:

117 Infringement by supply of products

(1) If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.

(2) A reference in subsection (1) to the use of a product by a person is a reference to:

(a) If the product is capable of only one reasonable use, having regard to its nature or design – that use; or

(b) If the product is not staple commercial product – any use of the product, if the supplier had reason to believe that the person would put it to that use; or

(c) In any case – the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.

Relevantly, the product information sheet for Apo-Lefluonomide stated:

"Apo-Leflunomide is indicated for the treatment of:

- *Active Rheumatoid Arthritis.*
- *Active Psoriatic Arthritis. Apo-Leflunomide is not indicated for the treatment of psoriasis that is not associated with manifestation of arthritic disease."*

[19] [2013] HCA 50

Issue

By the time the case came to the High Court, two particular issues arose:

- Could a method of medical treatment be a "manner of manufacture" and thus patentable?
- If a patent covers a method of treating a disease using a product, does another person infringe that patent by supplying that product with instructions that it be used to treat a different disease?

Decision

The majority of the High Court concluded that a method of medical treatment can be a "manner of manufacture" and "methods of medical treatment of human beings, can be the subject of patents".[20]

Crennan and Kiefel JJ in a joint judgment found that:

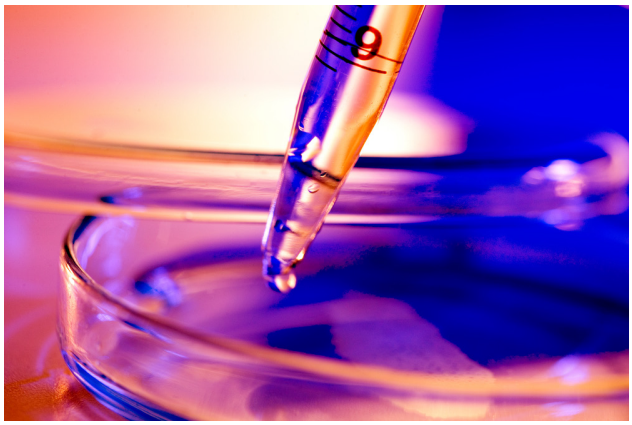
> *"Assuming that all other requirements for patentability are met, a method (or process) for medical treatment of the human body which is capable of satisfying the NRDC Case test, namely that it is a contribution to a useful art having economic utility, can be a manner of manufacture and hence a patentable invention within the meaning of s18(1)(a) of the 1990 Act.*
>
> *There is, however, a distinction which can be acknowledged between a method of medical treatment which involves a hitherto unknown therapeutic use of a pharmaceutical (having prior therapeutic uses) and the activities or procedures of doctors (and other medical staff) when physically treating patients. Although it is unnecessary to decide the point, or to seek to characterise such activities or procedures exhaustively, speaking generally they are, in the language of the NRDC Case, "essentially non-economic" and, in the language of the EPC and the Patents Act 1977 (UK), they are not "susceptible" or "capable" of industrial application. To the extent that such activities or procedures involve a "method or process", they are unlikely to be able to satisfy the NRDC Case test for the patentability of processes because they are not capable of being practically applied in commerce or industry, a necessary prerequisite of a "manner of manufacture."*[21]

The court held, in relation to section 117(2)(c), that as Apotex's instructions specifically said its product was not indicated for non-arthritic psoriaris, this was an "emphatic instruction to recipients of Apo-Leflunomide from Apotex to restrict use of the product to uses other than use in accordance with the patented method".[22] The section of the Act was not engaged as the product information document did not instruct recipients to use the unpatented pharmaceutical substance in accordance with the patented method.[23]

Further, the claim for indirect infringement failed as the court in relation to s 117(2)(b) concluded that it was not shown, nor could it be inferred, that Apotex had reason to believe that its product would be used contrary to the indications in the product information document.[24]

Each case will depend upon its particular facts, in particular the wording of the patent claim, and the infringing product and its use, however, the case is of interest:

- to health and medical researchers in terms of potential future patents in innovative methods of medical treatment; and
- to the life science industry in terms of the protection of their intellectual property. ■



[20] *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, [1] per French CJ. and [286].
[21] Id, at [286] per Crennan and Kiefel JJ
[22] Id, at [303] per Crennan and Kiefel JJ
[23] Id, at [303] per Crennan and Kiefel JJ
[24] Id, at [304] per Crennan and Kiefel JJ

Goodbye FMA and CAC - hello PGPA!

By Dr Tim Smyth, Special Counsel

The countdown to the commencement of the new *Public Governance, Performance and Accountability Act 2013 (Cth)* (**PGPA Act**) has begun. Commencement of the substantive provisions of this Act is planned for 1 July 2014. The PGPA Act will replace two Acts, well thumbed and bookmarked by both Commonwealth officials and their lawyers – the *Financial Management and Accountability Act 1997 (Cth)* and the *Commonwealth Authorities and Companies Act 1997 (Cth)* (**CAC Act**).

It is now time to get to know the PGPA Act.

The PGPA Act is a core part of a broader public sector management reform agenda which commenced in late 2010, with the announcement of the *Commonwealth Financial Accountability Review* (**CFAR**). The Department of Finance and Deregulation released 13 issues papers to Commonwealth agencies to facilitate discussion on financial management and performance. A Discussion Paper was released in March 2012, and more detailed proposals were outlined in a Position Paper in November 2012.

The PGPA Bill to consolidate the Commonwealth financial framework legislation into one Act was introduced into Parliament in May 2013. The Joint Committee of Public Accounts and Audit (**JCPAA**) conducted an inquiry into the PGPA Bill and tabled their report on 4 June 2012. The PGPA Act was passed by the Parliament on 28 June 2013 and received the Royal Assent on 29 June 2013.

The PGPA Act represents a change from a compliance approach to financial management, to a principles-based framework. The Act is based on four key principles:

- Government should operate as a coherent whole;
- a uniform set of duties should apply to all resources handled by Commonwealth entities;
- performance of the public sector is more than financial; and
- engaging with risk is a necessary step in improving performance.

A set of PGPA Rules and better practice guidelines are being prepared by the Department of Fniance to support the implementation of the PGPA Act. There will also be a review of other legislation to determine what consequential amendments are required.

Further background information is available on the Public Management Reform Agenda website of the Department of Finance – at www.pmra.finance.gov.au

The Act uses a number of key concepts:

- Commonwealth entities;
- Accountable authorities;
- Officials; and
- Public resources.

Commonwealth entities will be two types:

- **Corporate Commonwealth entities** established as corporations under their enabling Commonwealth legislation; and
- **Non-corporate Commonwealth entities** (Commonwealth government department and entities prescribed by the Rules).

Some parts of the PGPA Act apply to only one type of Commonwealth entity.

Accountable authorities are the persons or bodies responsible for governing the entity (eg secretary of the department or board of a corporate Commonwealth entity). Accountable authorities have a duty to govern the entity in a way that promotes the proper use and management of public resources (including effective systems relating to risk and control and keeping their Minister and the Finance Minister informed of activities of the entity and significant issues).

Officials are generally the staff of the entity. Staff of current CAC Act authorities will be officials under the PGPA.

Public resources include relevant money, relevant property and appropriations. Relevant money will include money in a bank account and any other money held or controlled by an entity.

Commonwealth entities should review their governance policies and procedures for compliance with the new legislation.

MEET THE TEAM

Tim Smyth

+61 412 868 174 • tim.smyth@holmanwebb.com.au

With degrees in medicine, law and business administration, Dr Tim Smyth is well known in the Australian health industry, having worked as doctor, Director of Medical Services, hospital manager, Area Health Service Chief Executive and Deputy Director General in the NSW Department of Health. Building on over 25 years of experience, he has an in depth understanding of the health industry and government. Tim's legal clients have included health services, government agencies, professional associations, health funds, research bodies, Divisions of General Practice, small and medium enterprises, service providers to the health sector and Australian subsidiaries of multinational companies.

Zara Officer

+61 2 9390 8427 • zara.officer@holmanwebb.com.au

Zara has practised insurance law and litigation in NSW for almost 20 years and is experienced in a broad range of insurance practice areas. She regularly acts for parties in NSW Coronial inquiries for public sector agencies and advises Government entities, insurers and self insurers on relevant statutory regulation in public sector litigation and liability. She has also worked in the public sector, starting her career at Royal Melbourne Hospital in general nursing and has direct experience working in a number of hospital settings, both private and public.

KEY CONTACTS:

Sydney

Alison Choy Flannigan
Partner – Corporate and commercial, regulatory, Health, aged care and life sciences
T: +61 2 9390 8338
alison.choyflannigan@holmanwebb.com.au

Tal Williams
Partner – Corporate and commercial, retirement homes and aged care
T: +61 2 9390 8331
tal.williams@holmanwebb.com.au

John Van de Poll
Partner – Medical malpractice and discipline
T: +61 2 9390 8406
jvp@holmanwebb.com.au

Robin Young
Partner – Workplace relations
T: +61 2 9390 8419
robin.young@holmanwebb.com.au

Zara Officer
Special Counsel – Medical malpractice and discipline
T: +61 2 9390 8427
zara.officer@holmanwebb.com.au

Tim Smyth
Special Counsel – Corporate and commercial, Health, aged care and life sciences
M: +61 412 868 174
tim.smyth@holmanwebb.com.au

Sandra Ivanovic
Senior Associate - Corporate and commercial, regulatory, Health, aged care and life sciences
T: +61 2 9390 8352
sandra.ivanovic@holmanwebb.com.au

Melbourne

Colin Hall
Partner – Medical malpractice and discipline
T: +61 3 9691 1222
colin.hall@holmanwebb.com.au

Brisbane

Mark Victorsen
Partner - Medical malpractice and discipline
T: +61 7 3235 0102
mark.victorsen@holmanwebb.com.au

For editorial enquiries or if you wish to reproduce any part of this publication please contact
Alison Choy Flannigan, Partner on +61 2 9390 8338 or
alison.choyflannigan@holmanwebb.com.au

Editor: Alison Choy Flannigan
Subeditor: Joann Yap

For all other enquiries please contact
Meta Lustig +61 2 9390 8456 or
meta.lustig@holmanwebb.com.au

HolmanWebb Lawyers

SYDNEY
Level 17 Angel Place
123 Pitt Street
Sydney NSW 2000
Phone +61 2 9390 8000
Fax +61 2 9390 8390

MELBOURNE
Level 10
200 Queen Street
Melbourne VIC 3000
Phone +61 3 9691 1200
Fax +61 3 9642 3183

BRISBANE
Level 13
175 Eagle Street
Brisbane QLD 4000
Phone +61 7 3235 0100
Fax +61 7 3235 0111

www.holmanwebb.com.au