Holman Webb
Lawyers

Health Law Bulletin

August 2011

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Holman Webb is proud to sponsor Research Australia's Cook for a Cure campaign to support health and medical research.

Introduction

Welcome to the August 2011 edition of the Holman Webb Health Law Bulletin, our inaugural edition.

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

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

Our team has recently been expanded with Alison Choy Flannigan joining us as a partner in our Sydney Office. Alison has held senior positions within the industry and has been recognised in Best Lawyers International: Australia and the Financial Review as one of the "best lawyers" in the area of health and aged care law. ■

Health, Aged Care and Life Sciences team.

National Health Reform - Corporate Governance in the New Era of Australian Healthcare

by Alison Choy Flannigan

The Council of Australian Governments (COAG) has agreed out of session in August 2011, the National Health Reform Agreement (2011) which is designed to deliver major reforms to the organisation, funding and delivery of health and aged care.

The reforms are aimed to achieve better access to services, improved local accountability and transparency, greater responsiveness to local communities and provide a stronger financial basis for Australia's health system.

There have been a number of key agreements in addition to the National Health Reform Agreement including:

- National Partnership Agreement on Improving Public Hospital Services 2011; and
- National Healthcare Agreement 2011.

Local Hospital Networks

Under the National Health Reform Agreement, the States are required to establish Local Hospital Networks by 1 July 2012.

The responsibilities of the Local Hospital Networks are set out in the National Health Reform Agreement.

Local Hospital Networks are to be established as separate legal entities under State legislation. The States will be accountable for financial management and audit of Local Hospital Networks. Local Hospital Networks will have separate bank account, will be able to receive funding from the National Health Funding Pool independent of State treasuries or health departments and will be audited as separate entities.

Local Hospital Networks will have a professional Governing Council and Chief Executive Officer. Their responsibilities are set out in the National Health Reform Agreement.

Local Hospital Network Governing Council members will be appointed under State legislation by State Health Ministers. Each Local Hospital Network's CEO will be appointed by the Governing Council, with the approval of the State Health Minister or their delegate, and will be accountable to the Governing Council.

Medicare Locals

Medicare Locals will be established by the Commonwealth by 1 July 2012. The strategic objectives for Medicare Locals are set out in the National Health Reform Agreement.

Medicare Locals will be independent legal entities (not government bodies) with strong links to local communities, health professionals and service providers, including GPs, allied health professional and Aboriginal Medical Services. It is expected that Medicare Locals will be companies limited by guarantee incorporated under the Corporations Act 2001 (Commonwealth).

The Australian Government published a Discussion Paper on Governance and Functions of Medicare Locals in November 2010 and there have been a number of submissions in response.

The Director-General of NSW Health published her report on Future Arrangements for Governance of NSW Health on 24 August 2011.

Governance Framework

Each and every one of the Local Hospital Networks and Medicare Locals should have already implemented a comprehensive and rigorous corporate governance framework, which applies to both the organisation and the Governing Council/Board.

This corporate governance framework should cover the following:

- Regulatory compliance, including the National Health Reform Agreement and State legislation
- Code of conduct and conflicts of interest
- Clinical governance
- Finance and solvency
- Managing stakeholder expectations, including consumers, health professionals and government
- Board committees – terms of reference, etc.
- Contractual obligations, including compliance with Commonwealth/State funding agreements
- Risk and audit
- Experienced and qualified members of the Board / Governing Council
- Delegation and remuneration
- Compliance with common law duties
- Compliance with other legal obligations, such as privacy laws, the Competition and Consumer Act 2010 (Commonwealth); Health Insurance Act 1973 (Commonwealth); occupational health and safety laws and workers compensation, environmental legislation, equal opportunity and anti-discrimination legislation
- Insurance and indemnity

Corporate Governance Challenges

There are a number of corporate governance challenges for Local Hospital Networks and Medicare Locals including:

- the challenge of balancing statutory, service and funding duties and the Corporations Act requirement of solvency, particularly when funding is tight; and
- the challenge for CEOs to be accountable to what is effectively two key supervisors, the Board/Governing Council on the one hand and the State Health Department/Commonwealth on the other. ■

Update on Advanced Care Directives

by Alison Choy Flannigan, Partner

Advanced care directives, also known as living wills or advanced care planning, enable a person over the age of 18, who is mentally competent, to express their wishes in relation to future medical care and treatment.

The common law in Australia recognises two relevant but in some cases conflicting interests:

i. a competent adult's right of autonomy or self-determination: the right to control his or her own body; and

ii. the interest of the State in protecting and preserving the lives and health of its citizens.[1]

Legislation and guidelines

Unfortunately, legislation dealing with advanced care directives is not uniform in Australia. In dealing with advanced care directives, you must have regard to the relevant legislation in your jurisdiction.

- Australian Capital Territory – The Medical Treatment (Health Directions) Act 2006 (ACT)
- New South Wales – NSW Health has published a Guideline on Using Advance Care Directives (GL2005_056)
- Northern Territory – The Natural Death Act 1988 (NT)
- Queensland – Guardianship and Administration Act 2000 (Qld)
- South Australia – Consent to Medical Treatment and Palliative Care Act 1995 (SA)
- Victoria – Medical Treatment Act 1998 (Vic)
- Western Australia – Guardianship and Administration Act 1990 (WA)[2]

National framework

In 2010 the Clinical, Technical and Ethical Principal Committee of the Australian Health Ministers' Advisory Council released a Consultation Draft for a National Framework for Advanced Care Directives, however, the final version is yet to be issued as at the date of writing this article.

Cases

In addition to the legislation, there have been a number of recent key cases, including:

- *Hunter and New England Area Health Service v A (by his Tutor) (2009) 74 NSWLR 88;*
- *Brightwater Care Group (Inc) v Rossiter (2009) 40 WAR 84;*
- *H Ltd v J (2010) 107 SASR 352.*

Hunter and New England Case

This case involved a patient Mr A, who was a Jehovah's witness, who attended a solicitor Mr N and appointed an enduring guardian.

In relation to dialysis, Mr A ticked "I refuse".

His Honour, McDougall J concluded that the direction represented a considered decision made by Mr A, and that when Mr A made that decision (and, to the extent that it may be relevant, when he was admitted to hospital), Mr A was in law capable of making the decision to refuse dialysis. The hospital was entitled to the declaration sought, that is, that the document was a valid "Advance Care Directive" given by Mr A, and that the hospital would be justified in complying with his wishes as expressed in that directive.

In that case, His Honour gave a summary of the relevant principles with emergency care decisions (whilst acknowledging that they will not apply in every conceivable circumstance):

i. except in the case of emergency, where it is not practicable to obtain consent (see para v. below), it is at common law a battery to administer medical treatment to a person without the person's consent. There may be a qualification if the treatment is necessary to save the life of a viable unborn child.

ii. consent may be express, or in some cases, implied; and whether a person consents to medical treatment is a question of fact in each case.

iii. consent to medical treatment may be given by the person concerned, if that person is a capable adult; by the person's guardian (under an instrument of appointment of an enduring guardian, if in effect; or by a guardian appointed by the Guardianship Tribunal or a court); by the spouse of the person, if the relationship between the person and the spouse is close and continuing and the spouse is not under guardianship; by a person who has the care of the person; or by a close friend or relative of the person.

iv. at common law, next of kin cannot give consent on behalf of the person. However, if they fall into one or other of the categories just listed (and of course they would fall into at least the last) they may do so under the Guardianship Act.

v. emergency medical treatment that is reasonably necessary in the particular case may be administered to a person without the person's consent if the person's condition is such that it is not possible to obtain his or her consent, if it is not practicable to obtain the consent of someone else authorised to give it, and if the person has not signified that he or she does not wish the treatment, or treatment of that kind, to be carried out.

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

vii. there is a presumption that an adult is capable of deciding whether to consent to or to refuse medical treatment, However, the presumption is rebuttable. In considering the question of capacity, it is necessary to take into account both the importance of the decision and the ability of the individual to receive, retain and process information given to him or her that bears on the decision.

viii. if there is a genuine and reasonable doubt as to the validity of an advance care directive, or as to whether it applies in the situation at hand, a hospital or medical practitioner should apply promptly to the court for its aid. The hospital or medical practitioner is justified in acting in accordance with the court's determination as to the validity and operation of the advance care directive.

ix. where there is a genuine and reasonable doubt as to the validity or operation of an advance care directive, and the hospital or medical practitioner applies promptly to the court for relief, the hospital or practitioner is justified, by the emergency principle, in administering the treatment in question until the court gives its decision.

x. it is not necessary, for there to be a valid advance care directive, that the person giving it should have been informed of the consequences of deciding, in advance, to refuse specified kinds of medical treatment. Nor does it matter that the person's decision is based on religious, social or moral grounds rather than upon (for example) some balancing act of risk and benefit. Indeed, it does not matter if the decision seems to be unsupported by an discernible reason, as long as it was made voluntarily, and in the absence of any vitiating factor such as misrepresentation, by a capable adult.

xi. what appears to be a valid consent given by a capable adult may be ineffective if it does not represent the independent exercise of the person's volition: if, by some means, the person's will has been overborne or the decision is the result of undue influence, or of some other vitiating circumstances.

Brightwater

In *Brightwater Care Group (Inc) v Rossiter [2009] WASC 229,* the Brightwater Care Group operated a residential aged care facility in Perth for people with disabilities.

Mr Rossiter was a quadriplegic who was mentally competent. He was generally unable to move and was only able to talk through a tracheotomy. He directed his medical service provider to discontinue the provision of nutrition and general hydration, the consequence of which he could die from starvation. He also requested the prescription of analgesics for the purposes of sedation and pain relief as he approached death.

Mr Rossiter was not terminally ill, nor was he dying. However, he had been advised that there was no prospect that his condition would improve, and in some respects, for example his eyesight, his condition was deteriorating.

Western Australia has specific provisions in its Criminal Code which imposes a duty to provide the necessaries of life, however, His Honour Martin CJ concluded that the Criminal Code did not impose upon Brightwater a duty to provide the necessaries of life to Mr Rossiter against his wishes. His Honour held that it is clear that Mr Rossiter had been provided with full information with respect to the consequences of any decision he might make and has the right to determine and direct the extent of the continuing treatment in the sense that treatment cannot and should not be administered against his wishes. If, after the provision of full advice, he repeats his direction to Brightwater that they discontinue the provision of nutrition and hydration to him, Brightwater is under a legal obligation to comply with that direction.

Such a direction is not irrevocable and while the patient retains his capacities, can be revoked by him at any time. ■

1. *Hunter and New England Area Health Service v A (by his Tutor T) (2009) 74 NSWLR 88, McDougall J2*

2. Note also legislation enabling Enduring Powers of Guardianship

Update on Personally Controlled Electronic Health Records – Legal and Privacy Issues

by Alison Choy Flannigan, Partner

As part of the 2010/11 Federal budget, the Government announced a $466.7 million investment over two years for a national Personally Controlled Electronic Health Record (PCEHR) system for all Australians who choose to register on-line, from 2012-2013. This initiative has the potential to be a revolutionary step for Australian health care, in terms of both consumer's access to their own health information and improvement in information which will be available to health professionals when they treat a patient.

A number of major steps have been taken to implement the PCEHR including Wave 1 and Wave 2 implementation as well as the release by the Australian Government of the draft Concept of Operations: relating to the introduction of a Personally Controlled Electronic Health Record (PCEHR) system in April 2011.

The draft Concept of Operations provides an overview of what the PCEHR System is and how it is proposed to work.
Some key concepts are:

- Individuals will be able to choose whether or not to have a PCEHR and will be able to set their own access controls and may withdraw at any time.
- The PCEHR will contain clinical documents such as Shared Health Summaries, Discharge Summaries, Event Summaries, Pathology Result Reports, Imaging Reports and Specialist Letters. It may also include key health information entered by the individual such as over-the-counter medicines and allergies and access information from Medicare Australia such as an individual's organ donor status, dispensed medications funded under the PBS, information about healthcare events from an individual's Medicare claiming history and a child's immunisation history. The PCEHR may also contain an individual's advance care directives (if any). The PCEHR is, however, not a comprehensive health record.
- Healthcare organisations can choose to participate and will need a healthcare organisation identifier (HPI-O). They must agree to use appropriate authentication mechanisms to access the PCEHR and use software that has been conformance tested to be used with the PCEHR system.
- Health information within the PCEHR system will be protected through a combination of legislation, governance arrangements and security and technology measures.

The Australian Privacy Commissioner provided a submission in response to the draft Concept of Operations in June 2011.

There are a number of medico-legal and privacy issues which arise with the PCEHR. Some of these are summarised below:

Medico-legal

- If a medical practitioner consults with a patient and is negligent in entering information onto the PCEHR, there are more clinicians relying upon it, so the potential for liability from a negligent assessment of a patient or negligently prepared medical record increases.
- Health professionals must be mindful that the PCEHR is not a complete medical record and must continue to be vigilant in continuing to obtain independent information from patients. Information may be excluded from the PCEHR at the request of a patient and missing information is unlikely to be flagged.
- If a medical practitioner has relied upon information on the PCEHR which is incorrect, then the medical practitioner will need to track the author of the original information to join as a cross-defendant.
- If a patient instructs a medical practitioner not to include information on the PCEHR then the medical practitioner will be under an obligation to inform the patient the risks and consequences of this.
- Direct access to a medical record may be denied if providing access would pose a serious threat to the life or health of any individual. In those cases, the patient is usually provided access through another medical practitioner. If consumer access requests are dealt with centrally, measures should be implemented to ensure that a clinical assessment is made in relation to whether or not a patient's request for access or information could pose a serious threat to the life or health of any individual. Arguably such information should not be included in the PCEHR.
- Often a request for access can be an indicator of a potential claim which can be resolved quickly by the clinician by early discussions with the patients. There should be a mechanism so that relevant clinicians are informed if there is a potential claim early.

Privacy issues

There are also a number of privacy issues, including:

- Obtaining adequate privacy consent from patients;
- Ensuring that the systems can accurately implement the consent options of patients, such as limiting access or prohibiting access to the PCEHR to health professionals nominated by patients.
- Ensuring that only information which is required to provide treatment for the patient is collected.

- Privacy issues if the system involves a number of system vendors and subcontractors or cloud computing.
- Uniformity of the usage of medical terms and abbreviations and clear handwriting is preferred to protect data quality.
- Clear understanding of the information flows and potential for leakage of personal health information to unapproved persons or overseas.
- Data security issues.
- Patient and participating health professional identification and verification issues.
- Education and training of participating health professionals.

Mental Health Case Update – Crowley v Commonwealth of Australia, Australian Capital Territory and Pitkethly

by Alison Choy Flannigan, Partner

The recent case of *Crowley v Commonwealth of Australia, Australian Capital Territory and Pitkethly [2011] ACTSC 89* is authority for the proposition that a mental health service provider can be held negligent in relation to, amongst other matters, failing to pursue a patient's admission to hospital, even if assessed at the time as no risk to themselves or others.

In that case Jonathan Crowley, a 34 year old man, suffered a psychotic episode. On Monday, 10 December 2001, family members (his sister who was a medical practitioner) made contact with ACT Mental Health Services **(ACTMH)**, and an ACTMH psychologist visited the family home that night.

Jonathan believed he was Jesus and exhibited poor judgement. He had used cannabis, apparently in fairly high quantities, for many years.

Before the events in December, he had not been a patient of the ACTMH, nor had he had any psychiatric admissions, or been seen by any specialist psychiatrist.

It was agreed that Jonathan needed assessment in hospital, and there were discussions as to how this would be arranged.

Mr Wells, clinician with ACTMH attended the home and ascertained that Jonathan was not a danger to anyone, or to himself. However, the Court held that there were some significant issues mentioned in the forms completed by Mr Wells.

These included:

- Jonathan's report of having met Judas who had subsequently hanged himself, and of having been "tussling with the devil who had crushed his hand";
- That Jonathan did not get on with the Police;
- That when Jonathan was coming off marijuana he was usually angry and aggressive and punched holes in the walls;
- That Jonathan's parents had assured Mr Wells that "they could manage him overnight";
- That Jonathan was tall (around 180cm and strongly built, with curly shoulder-length dark hair);
- That Jonathan was unlikely to agree to psychiatric treatment and that an involuntary admission would probably be required to assess and control risks and commence treatment;
- Mr Well's suggestion to the Crowley family that the Crisis Team could visit "after about 9am" on Tuesday "to see if we could get him to agree to come to hospital voluntarily for a psych reg assessment";
- Mr Well's advice that if Jonathan was unwilling to go voluntarily, "we would most likely leave and return with police to take him to hospital";
- The Crowley family's statement that they "would prefer that Police not be involved but were aware that they may be required."
- Jon Wells marked the risk assessment for "non-compliance/absconding" as "high" (an upgrade from the earlier "moderate" risk). He also wrote on the Crisis Team whiteboard the plan specifying that the Crisis Team should phone Keith Crowley to organise a visit to assess Jonathan early the next morning.
- Mr Crowley stayed with Jonathan that night until around 1:00 am or 2:00am, at which stage Jonathan seemed to be sleeping soundly.

Jason Morris, a rehabilitation office with the ACTMH co-incidentally attended the Crowley home on Tuesday morning to take Mark Crowley, Jonathan's brother, to a rehabilitation activity. He thought Jonathan was "different to his usual self". Jason had observed Jonathan talking to himself and had with him a long black item which we waved around his head in a demonstrative rather than aggressive way. This was not reported for two hours.

No hospital admission was achieved before Jonathan left the family home on Tuesday morning carrying a kendo stick, an instrument consisting of several pieces of bamboo held together and covered.

For some time, Jonathan wandered the streets near his home. He was reported to the police.

Police officers came upon Jonathan in Doyle Terrace, Chapman. Shortly thereafter Senior Constable Pitkethly shot Jonathan in the neck. He sustained injuries as a result of being shot that left him suffering quadriplegia.

Whilst the police officers were held to be negligent, this article concentrates on issues for the ACTMH.

The Court inferred that neither Mr Wells nor any other ACTMH staff member gave any member of the Crowley family clear advice that, until he could be admitted to hospital, Jonathan had to be supervised closely, rather, they encouraged the Crowleys to "just keep and eye on him", a very different message.

The claims against the ACTMH are summarised as follows:

- The ACTMH is said to have been negligent in its failure to provide information and training to the Australian Federal Police in how to deal with persons acting in an aberrant manner (in particular about the appropriate use of OC spray in dealing with persons acting in an aberrant manner);
- The ACTMH is said to have been negligent in the failure by its staff on the Tuesday to follow up and implement Jon Well's Monday night plan for further assessment and treatment of Jonathan, and the specific failure to facilitate Jonathan's admission to hospital on the Tuesday;
- Jason Morris's failures to pass on his observations of Jonathan to the Crowley family, and to pass on those observations to ACTMH colleagues until two hours after making them, are said to have been negligent;
- ACTMH is said to have been negligent in relation to its record-keep activities, particularly in relation to the recording of Jonathan's information, in its failure to connect the person being sought by police with its patient Jonathan Crowley, in its failure to give Police information about Jonathan that was in the ACTMH records and generally in failing to respond appropriately to policy inquiries about the person who was in fact Jonathan.

His Honour Penfold J held:

- From Monday night, when Jon Wells arrived to conduct a preliminary assessment on Jonathan, the ACTMH owed a common law doctor-patient duty of care to exercise reasonable care and skill in the provision of professional advice and treatment to Jonathan as its patient;
- Deciding whether to exercise the power of involuntary admission requires a careful balancing of the need to protect sufferers of mental illness from recognised forms of harm and the need to adopt the least restrictive approach to doing so.
- The ACTMH breached its duty of care to Jonathan in failing to pursue Jon Well's plan for Jonathan's admission to hospital and in failing to assess Jonathan again and facilitate his admission to hospital on the Tuesday morning, noting that facilitating does not necessarily imply achieving but only making easier or helping forward;
- Jason Morris breached ACTMH's duty of care to Jonathan in failing to pass on to the Crowley family the odd, unsupervised behaviour of a family member who to his knowledge was already the subject of an ACTMH plan for admission to hospital.
- The failure of the ACTMH staff to pursue the reasons for the police interest in the person the police had asked about, and to raise the possibility that Jonathan was the person police was interested in, with the police, either immediately or after pursuing that possibility with the Crowley family, was a breach of its duty of care to Jonathan as its patient.
- His Honour considered the High Court case of *Stuart v Kirkland – Veenstra* and stated that the case does not seem to be authority for a proposition that there could never be a duty of care on a mental health authority to exercise an available power to detain.
- Jonathan's injury was caused by the negligence of the police and the ACTMH breached its duty to Jonathan in several respects. The question was did the Police breach the chain of causation?
- His Honour applied the "but for" test and held that the acts of the ACTMH were genuine contributors to the situation in which the Police found themselves and the Police actions were not causally independent of ACTMH's actions.
- As a result, the breaches of ACTMH was causative of Jonathan's injuries. The amount of damages was to be agreed between the parties. ■

Professional Misconduct and Inappropriate Prescribing – Medical Board of Australia v Saykao.

by Zara Officer, Special Counsel

A recent case from the Victorian Civil and Administrative Tribunal (VCAT) underlines the importance for doctors to establish and then to document that a therapeutic need exists when issuing prescriptions, particularly when prescribing substances that are open to abuse. It also underscores the importance of keeping adequate clinical notes. Failure to do so may expose a practitioner to findings of unprofessional conduct. The case also provides an example of conditions being imposed that are apparently unrelated to the original complaint.

Dr Saykao was born in Laos and wanted to be a doctor from the age of 12. He completed his medical studies at Monash University in 1980 and is reportedly only the second Hmong to gain a medical qualification in the world, and the first to be involved in primary care of patients. Most of his patients came from the Hmong community and in recent years his practice expanded to include a number of refugee and immigrant groups. He practices medicine in Victoria and assists members of the Hmong community bridge the gap between cultural and western medicine, spending much of his out of clinic time responding to emails from members of the Hmong community concerned or confused about advice they have received from their own medical practitioners. These activities are mentioned in the decision, but were not the subject of the complaint.

Complaint

The complaint against Dr Saykao concerned a patient to whom he inappropriately prescribed anabolic steroids and other androgen medication on many occasions.
The allegations were threefold:

1. that Dr Saykao failed to take all reasonable steps to ensure that a therapeutic need existed before prescribing anabolic steroids and androgen medication. It was alleged he prescribed excessive anabolic steroids when he knew or ought to have known that they were being used for non-therapeutic purposes;
2. that the clinical notes of Dr Saykao's consultations with his patient were non-existent and/or inadequate; and
3. that on or about 18 February 2009 Dr Saykao pleaded guilty in the Magistrates Court in Victoria to 14 charges of prescribing a drug of dependence without ensuring a therapeutic need.

Facts

The patient had first attended Dr Saykao's practice on 26 May 2006 and requested growth hormone to increase vigour. Dr Saykao obtained certain pathology results from the patient's previous doctor on 30 May 2006 and then prescribed Genotropin 2.0mg in injectable form. This was subsequently prescribed in June and September 2006.

Dr Saykao did not conduct blood or other medical tests to ascertain whether there was a genuine therapeutic need.

In 2007 the same patient attended Dr Saykao and over ten separate consultations during the period July to September 2007 Dr Saykao provided prescriptions for testosterone related medication. Dr Saykao did not take a fully documented clinical history or examination. He did not conduct tests to ascertain the patient's testosterone levels. There were no clinical notes of the patient's clinical history, symptoms or clinical examination findings or a diagnostic conclusion. There was no recorded discussion of possible alternative treatment. There was no established androgen deficiency indicating a need for the prescriptions.

Two different pharmacists voiced concerns to Dr Saykao about dispensing the medications prescribed, on the basis of the quantity and the frequency of the patient's request for the medication. Ms Lang, pharmacist refused to dispense further prescriptions. The second pharmacist, Mrs Hose, raised concerns but Dr Saykao confirmed that she should continue to fill the prescriptions.

Both pharmacists contacted the Department of Health in Victoria to express their concerns about Dr Saykao's prescribing to the patient. An investigation ensued and an application was made to the then Medical Practitioner's Board of Victoria. The matter proceeded to the Victorian Civil and Administrative Tribunal (VCAT) for hearing.

Findings

VCAT made the following findings:

4. that Dr Saykao had engaged in professional misconduct by inappropriately prescribing anabolic steroids and other androgen medication to his patient.
5. that Dr Saykao had engaged in unprofessional conduct and that his clinical notes of his consultations with this patient were non-existent and/or inadequate.
6. that Dr Saykao engaged in unprofessional conduct on the basis that a finding of guilt was made against him in the Magistrates Court in respect of 14 charges of prescribing a drug of dependence without ensuring a therapeutic need. (Dr Saykao had pleaded guilty in the Magistrates' Court. No conviction was entered but Dr Saykao was placed on a good behaviour bond and ordered to pay $1,400 to the Victorian Bushfire Fund.)

Penalty

Dr Saykao had altered his practice of prescribing drugs such as testosterone. He refused to give repeat prescriptions and if more than one injection was required he kept the drugs in a securely

locked cupboard and asked the patient to return to him personally for further injections.

Consequently the parties at the commencement of the hearing handed up a joint submission as to determination and penalties. Dr Saykao was cautioned and reprimanded for his prescribing to the patient and for his clinical note taking. Conditions were placed on Dr Saykao's registration. These include:

- A requirement that Dr Saykao undertake further education in relation to dealing with difficult patients and in prescribing practices.
- A requirement to undertake a period of supervision by an experienced full time senior general practitioner *with experience in integrated medicine. The topics to be covered to include an understanding of potential boundary issues when providing information to others in his community and assist them with their communication with their medical practitioners*.
- A requirement to report to the Medical Board of Australia with respect to these conditions.

The Tribunal noted an apparent lack of understanding by Dr Saykao about prescribing anabolic steroids particularly when faced with a difficult and demanding patient. Therefore, the order for further education and supervision of this aspect of his practice is appropriate. Those conditions were proffered jointly by the parties. The conditions in italics were inserted by VCAT, not on the motion of the parties.

There is nothing in the reasons for decision suggesting that the patient was of Hmong background or that Dr Saykao had assisted that patient with their communications with other medical practitioners.

Therefore the conditions inserted by VCAT for Dr Saykao's supervision to cover potential boundary issues concerning the Hmong community do not appear to relate to the issues which were dealt with in the complaint, namely prescribing practices. VCAT noted that Dr Saykao had an interest in integrated medicine and noted also that he is a Shaman. On that basis they required the supervisory general practitioner to have experience in integrated medicine.

Dr Saykao had informed the Tribunal that he provided his Hmong community members with information and assisted them in communicating with their medical practitioners, but he did not provide them with medical advice. Dr Saykao's strong commitment to the Hmong community was noted, as was his out of clinic time responding to emails from members of the community concerned or confused about advice they received from their own practitioners. On that basis, although unrelated to the complaint, VCAT determined it was appropriate that the topics to be covered in his supervision include an understanding of potential boundary issues when providing information to his community members when assisting them in their communication with their medical practitioners. As at the date of publication we are unaware of any appeal from this aspect of the orders. ■

Medical experts – Liability as expert witnesses

Bruce Cussen, Partner and Vahini Chetty, Solicitor

Medical professionals are often called to give expert evidence in matters before the courts. To date, they have given that evidence with immunity from prosecution. If recent developments in the United Kingdom are adopted in Australia, that immunity may be at risk.

In *Jones v Kaney [2011] UKSC 13*, the United Kingdom Supreme Court lifted the long-entrenched immunity from prosecution historically granted to expert witnesses In that case the Supreme Court recognised that the duties owed by expert witnesses are more akin to the duties owned by barristers or counsel than by lay witnesses. Lay witnesses were found to owe a single duty to the court, whereas the duty owed by barristers and expert witnesses were twofold – owed to both the client and the court.

For the past nine years barristers in the UK have not enjoyed immunity from prosecution arising out of their conduct in legal proceedings. Statistics before the Court in *Jones* showed that despite the lack of immunity, there did not seem to be an increase in proceedings brought against barristers since the lifting in 2002 nor was there any reluctance on the part of barristers to take on cases. Following from this the Court in Jones found that since barristers no longer enjoyed immunity and the removal of barristers' immunity did not seem to result in undesirable consequences, it was prudent to abolish the immunity that until then was granted to expert witnesses.

It has been long-established in Australia that witnesses are immune from being sued by the party that engaged their services for negligence or breach of contract: *Cabassi v Villa (1940) 64 CLR 130*. This principle applies to both lay witness and expert witnesses alike as no distinction is generally made between the two. However, since Australian courts often consider the decisions made by UK courts, it is important to consider whether the position will change in Australia.

The issue of immunity of medical experts in Australia was considered as recently as 2006 in the case of *James v Medical Board of South Australia and Keogh [2006] SASC 267.*
The facts are as follows:

- Dr James was a forensic pathologist who was asked to give evidence in relation to the prosecution of

Mr Keogh for murder. Dr James' manager, Dr Manock, had conducted the post mortem. Mr Keogh was convicted (at least in part) on the basis of Dr James' evidence.

- Following the guilty verdict, Mr Keogh brought a complaint against Dr Manock to the then Medical Board. Dr James provided evidence in support of Dr Manock in these proceedings.
- Mr Keogh then lodged a complaint with the Medical Board against Dr James based on inconsistencies in the evidence which he provided at trial and in Dr Manock's Medical Board proceedings.

The Full Court of the Supreme Court of South Australia in *James v Medical Board of South Australia and Keogh [2006] SASC 267* considered whether such a claim could be brought against Dr James as, in both cases, he had acted only as an expert witness and expert witnesses are immune from prosecution. But it is relevant to note that the case it was considering (the disciplinary case) did not involve a court, but Dr James' professional body, to which, under the rules of his profession, Dr James was accountable.

It was held to be in the public interest that, although immune from suit for the evidence given, expert witnesses should be held accountable to their professional peers for complaints brought by members of the public for unprofessional conduct arising out of the provision of that evidence.

Special leave to appeal to the High Court of Australia was refused: [2007] HCATrans 107.

Similarly, an application for special leave to appeal to Mr Keogh against Dr James which could have concerned questions as to the duty of expert witnesses was dismissed because the grounds of appeal were directed to attacks on findings of fact which were difficult to overturn and no question of public importance was raised by the application: *Keogh v James [2010] HCASL 36.*

Accordingly, the position in Australia is that although expert witnesses are immune from prosecution for evidence that they give, they may still be brought before a professional body for unprofessional conduct.

It seems unlikely that the position in Australia in relation to the immunity will change in the immediate future. However, there are steps that expert witnesses can take to minimize any potential liability. These steps are as follows:

i. A paramount duty of care is owed to the court. This duty requires experts to be truthful at all times. In providing expert reports and professional opinion, experts should be mindful of this duty. "Hot-tubbing", or the provision of a joint report by expert witnesses has now become common practice. This might increase the temptation for experts to simply agree with what is being said by the other expert with whom they are conferring.

ii. Experts need to ensure that they always bear the following in mind when providing joint statements:

   a. Always ensure that they have read the report of the opposing expert before engaging in a discussion or conference with that expert;

   b. There is no obligation upon them to agree with anything that they do not believe. They should not let their professional opinion be swayed by the opposing expert;

   c. Professionals should always ensure that they are thorough in their consideration of the issue at hand and that they always provide their true evaluation of the situation; and

   d. Always read joint statements thoroughly before signing them.

iii. When agreeing to provide expert evidence, include in any contractual retainer a clause excluding liability for any issues arising out of the evidence which is given. In that way there is additional protection from legal action in the event that immunity is later lifted. It will not, however prevent claims being brought by a professional body.

If experts provide their opinion according to the above steps, this should assist them in avoiding both litigation and proceedings from the professional body. Of course, expert witnesses should also ensure that they have appropriate insurance coverage in place. ■

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Expert witnesses should be held accountable to their professional peers for complaints brought by members of the public for unprofessional conduct arising out of the provision of that evidence.

Update on Pharmaceutical Benefit Scheme (PBS) Reforms

Alison Choy Flannigan, Partner

Medicines Australia MOU

On 6 May 2010 (re-signed 28 September 2010), the Commonwealth Government and Medicines Australia signed a Memorandum of Understanding with effect until 30 June 2014. The intent of the MOU was to:

.."promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy."

The MOU covered the following issues:

- strengthened price disclosure arrangements
- price reductions for certain medicines listed on the PBS
- the creation of new therapeutic groups
- the consistent treatment of brands of medicines sold at the same price
- comparators
- parallel TGA and Pharmaceutical Benefits Advisory Committee (PBAC) evaluation and assessment processes
- a managed entry scheme from 1 January 2011
- timing and maximum timeframes for PBS pricing negotiations and consideration by Cabinet and
- resolution of issues in good faith.

The National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010 (Commonwealth) was passed to implement these arrangements.

Announcement of listing deferrals

On 25 February 2011, the Minister for Health and Ageing, the Hon Nicola Roxon MP, announced the deferral of the listing of seven medicines under the PBS. The explanation was that, for those medicines which had been deferred, there were existing or alternative treatments that are already available or there is no additional clinical benefit.

The Government also announced that all listings with a financial impact will now be considered by Cabinet. The deferral of the listing was characterised as a cost saving measure.

This was an extraordinary change from previous Government policy in which it was extremely rare for a medicine which had received a positive response from the PBAC – an independent body comprised of doctors, health professionals and consumer representatives – to not be listed.

Previously only medicines that had a financial impact of $10 million or more would require Cabinet approval.

In view of significant stakeholder concern, the Government announced a Senate Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme. A number of industry submissions were provided.

The Senate Finance and Public Administration References Committee tabled its report on the Government's Administration of the Pharmaceutical Benefits Scheme in Parliament on 17 August 2011.

The Committee concluded that the decision to defer the listing of certain medicines under the PBS, despite positive recommendations by the PBAC, and the decision to subject all future listings with financial implications for the budget to Cabinet review, constitutes a "major, unnecessary and unwelcome" change to Government policy. "This profound and ill-considered change in policy puts at risk affordable access to medicines for Australians, and will have significant consequences for the pharmaceutical sector, including research and development.

The committee acknowledged Government's responsibility to be mindful of budgetary constraints, however, it considers that responsible fiscal management should be applied at a whole of government level as opposed to trying to create savings through "piecemeal and ill-advised policy changes".

The Government announcement came as a complete surprise to industry, consumer and patient groups alike and constituted a significant departure from previous policy. Such a change was a possible contravention of at least the spirit of the MOU with Medicines Australia and will have repercussions when it comes to future negotiations with industry.

The committee was concerned that the change of policy will lead to a politicisation of the listing process and would irreversibly damage the independence and reputation of the PBAC.

The committee was very concerned about the uncertainty which has arisen from the Government's decision to defer the listing of medicines. The added layer of uncertainty will undoubtedly impact on investment decisions by the pharmaceutical sector, to the detriment of health consumers.

The Committee considered that the unprecedented changes introduced by the Government to the listing of medicines in Australia was "unacceptable and is based on short-term and ill-conceived policy goals".

The Committee made the following recommendations:

- The committee recommends that the Government withdraw the statement made on 25 February 2011 regarding the deferral of the listing of new medicines and the new rules applying to listings from that point forward.
- The committee recommends that the Government retract the statement that PBAC listing recommendations will not be proceeded with until savings are found to offset the costs of listing those medicines under the PBS.
- The committee recommends that the Government should explicitly state that it rejects any implication that the listing of new medicines requires savings to be made elsewhere in the health portfolio.
- The Government should reinstate its commitment to making an explicit decision regarding the listing of new medicines on the PBS within the terms and intent of the Memorandum of Understanding signed with Medicines Australia on 6 May 2010 and re-signed on 28 September 2010.
- That the Government reinstate the "$10 million rule" so that medicines that have a financial impact of less than $10 million in each year over the forward estimates can be listed on the PBS Schedule by the Minister without waiting for Cabinet approval.

At the time of writing this article, the Government has yet to formally respond to the Senate Report. ■

Accommodation Bonds – Changes to the Aged Care Act

by Tal Williams, Partner

The Commonwealth Government has recently introduced the *Aged Care Amendment Act 2011* **(the Act)** which came into effect on 26 July 2011. Prior to the introduction of this Act the Government had identified a lack of clarity in relation to the way that aged care providers could use accommodation bonds. They perceived that the original policy intent had not been clearly articulated in the legislation and that, with the increase in amount of accommodation bonds being held (from $500 million in 1997 to more than $10.6 billion in 2010) the issue needed to be addressed.

Accommodation bonds are principally an unsecured loan paid by the care recipient to a provider.

The Act now prescribes that accommodation bonds can only be used by approved providers for:

i. capital works,

ii. investment in financial products,

iii. obtaining loans for this purpose; and

iv. refunding accommodation bonds.

These limitations have the potential to create cash flow issues for providers and accordingly the previous restrictions on the use of income derived from the bonds, retention amounts and accommodation charges has been lifted.

As readers would be aware, Productivity Commissioner's report (issued on 8 August 2011) has identified the need for reform in the industry and has identified that the tight financial margins that exist in the private, not for profit or Government sectors. In this context the penalty for breaching the Act ($33,000 per offence) is a penalty that providers in the industry can ill afford. Where there is misuse of accommodation bonds criminal charges can now be laid.

The Department of Health and Aging has also been provided with greater powers to enable them to monitor and investigate utilisation of accommodation bonds, particularly in instances where approved providers are experiencing financial difficulties or appear to be utilising the bonds for non permitted uses.

These changes take effect from 1 October 2011 however a 2 year transition period has been permitted to enable the sector to familiarise itself with the new requirements.

Providers should review the legislation as soon as possible and to ensure that they comply. Do not hesitate to contact us if you require any assistance in that regard. ■

Harmonisation of Workplace Safety Laws

by Robin Young, Partner and Nick Read, Solicitor.

Important new laws have been enacted to harmonise the different state laws around Australia into a national code and will affect how an organisation should ensure the health and safety of workers and others that might be put at risk by their work.

Changes to the Occupational Health and Safety Act 2000 (NSW) (OHS Act) commenced in June 2011 and a new Workplace Health and Safety Act 2011 has been passed in NSW which will commence on 1 January 2012.

These are some of the changes.

Expanded Coverage

The meaning of "worker" has been redefined and is now not only an employee, but can also include contractors or sub-contractors (employees of both), employees of a labour hire company, outworkers, work experience students or volunteers.

New Primary Duty of Care

The duty of care is now to ensure the health and safety of workers "as far as reasonably practicable". The High Court has held that, in any prosecution of a workplace safety offence, the prosecutor must identify the measures that should have been taken to prevent the incident. The prosecutor now bears an additional burden of proving that the measure that should have been taken was reasonably practicable.

For best practice, organisations should take into account how likely a risk to health and safety is, the degree of harm that could result, what is known about the risk and the ways in which it can be eliminated. The cost associated with risk minimisation can also be considered.

Common sense works best. Working at heights without fall protection, for example, is obvious and elimination of this risk with harnesses, fencing and handrails, are well known prevention measures.

The new officer offence

The liability provision for directors has been removed from the OHS Act, but directors (and high-level management) now have a new positive obligation to exercise due diligence. This means developing (or maintaining) systems with up to date knowledge of health and safety matters and industry risks as well as directing resources toward compliance.

Consult and cooperate

Businesses must consult with workers under formal processes in the new laws and there are new powers for Health and Safety Representatives. When a number of organisations are working together on the same project they are required to consult and cooperate on safety matters.

Conclusion

The changes in NSW are part of the development of a consistent national approach to occupational health and safety which is intended to increase communication and cooperation to ensure the health and safety of workers and those affected by an organisation's operation to reduce serious injuries and deaths in Australian workplaces.

We recommend an immediate gap analysis of existing systems and to set about implementing new polices to ensure compliance with the new duties. Existing contracts should also be reviewed to ensure the new consultation requirements are met. ■

Food Safety Update for Hospitals and Aged Care Facilities

by Rachael Sutton, Partner

Since October 2008, all food businesses throughout Australia that provide food service to "vulnerable populations", such as hospitals and aged care facilities, have been required to develop and implement a Food Safety Plan (FSP).

Vulnerable persons include people over 65, children under 5, people who suffer low immunity and pregnant women. Their vulnerability means they are more at risk of food borne illness or can develop more severe conditions from it than the general population.

The pathogen of greatest concern is Listeria monocytogenes (LM). LM is the causative agent of listeriosis, a potentially fatal illness in at risk people. While the incidence of listeriosis is relatively low, it is important because of the high case-fatality rate of this infection. Eating contaminated foods is the most common means of contacting this illness. Other pathogens such as salmonella can cause more severe illness in some vulnerable persons.

Businesses catering specifically to these groups need to take considerable care when sourcing, preparing, storing and serving foods. The high risk nature of vulnerable persons is supported by food borne illness outbreak data which indicates a higher prevalence of food borne-related illness and deaths in care facilities when compared to the general population.

A review conducted by the NSW Food Authority (Authority) identified 67 outbreaks between 1995 and 2008 involving food service to vulnerable populations. Within these facilities the types of food handling operations differed significantly and management of these risk relies on the implementation and development of a FSP.

In NSW, businesses which are required to hold a license pursuant to the Vulnerable Persons Food Safety Scheme of the Food Regulation (NSW) 2010, and have an audited FSP in place[1] are:

- acute care hospitals,
- psychiatric hospitals,
- nursing homes for the aged,
- hospices,
- same day establishments for chemotherapy and renal dialysis services,
- respite care establishments for the aged,
- same day aged care establishments,
- low care aged care establishments,
- delivered meals organisations, and
- childcare centres (not currently implemented in NSW).

FSPs must comply with the requirements of Standard 3.2.1 of the Food Standards Code (FSC) and:

- systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business,
- identify where, in a food handling operation, each identified hazard can be controlled, and the means of control,
- provide for the systematic monitoring of those controls, provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control,
- provide for the regular review of the program by the food business to ensure its adequacy, and
- provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.

In NSW the FSP may be audited for compliance by the Authority or a person approved by the Authority under s 87 of the Food Act, 2003 (NSW). Auditors issue reports to the Authority and may also Corrective Action Requests **(CARs)**. The Authority can take enforcement action (improvement, prohibition notices, fines or prosecutions) where deficiencies are detected.

The consequences of not having an appropriate FSP that is complied with and audited regularly for compliance with the FSC can be serious for the persons being cared for by the business and the business itself. Whilst there have not been any prosecutions against businesses licensed under the Vulnerable Persons Food Safety Scheme at this point in time there have been prosecutions of a number of other food businesses (in the areas of fast food retail and ready to eat meat products) for failing to comply with their FSP in respect to listeria and salmonella management and outbreaks which have resulted in serious health consequences for persons who have consumed their food. ■

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1. Standard 3.3.1 of the Australia New Zealand Food Standards Code, titled 'Food Safety Programs for Food Service to Vulnerable Persons', was gazetted 5 October 2006 and commenced 5 October 2008

MEET THE TEAM

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Alison has over 20 years experience in advising health industry clients in many areas of corporate and commercial law. Alison's clients include public and private hospital operators and health care providers, private health insurers, biotechnology, pharmaceutical and aged care/retirement living clients.

She has held a number of industry positions including General-Counsel, Corporate and Commercial of one of Australia's largest private hospital operators, Company Secretary of Research Australia and a member of public hospital advisory committees.

In 2008-2011 Alison was nominated by her peers in Best Lawyers International: Australia and in the Australian Financial Review as one of Australia's "best lawyers" in the area of health and aged care.

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John has more than 15 years experience in Health Law, both in medical negligence and medical discipline. John leads the Sydney medical malpractice team at Holman Webb and acts for leading MDO's.

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John's extensive experience in defending medical malpractice claims, assisting practitioners through disciplinary processes and acting for a number of medical defence organisations has given him an in depth understanding of trends in the health industry.

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