

# Health Law Bulletin

June 2018



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## Introduction

Welcome to the June 2018 edition of the Holman Webb Health Law Bulletin.

It is not possible to escape recent press about the Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry.

Some of the behaviours presented in the testimony of witnesses include:

- misleading regulators;
- charging people for products and services that they did not receive; and
- failing to compensate people in a timely manner.

The Royal Commission has raised serious governance issues.

Whilst banking, superannuation and finance is a different industry to the health and aged care sector, there are lessons to be learnt for every Board in Australia. A fundamental principle supporting governance is that Boards are accountable for the culture of their organisations, including accountability and transparency. Similar to banks, the health and aged care sector can greatly affect the lives of vulnerable consumers.

This Health Law Bulletin discusses issues such as:

- corporate and clinical governance;
- aged care quality reforms;
- exclusion zones for reproductive health facilities;
- recent cases such as *Sparks v Hobson; Gray v Hobson [2018] NSWCA 29*; and
- updates to the National police check application process.

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

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

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

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

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 lifesciences

Holman Webb Lawyers

T: (02) 9390 8338 M: 0411 04 9459

E: [alison.choyflannigan@holmanwebb.com.au](mailto:alison.choyflannigan@holmanwebb.com.au)



# Corporate and Clinical Governance Update for Health and Aged Care Providers

by Alison Choy Flannigan, Partner

## 1. What is Corporate Governance?

Corporate governance is a broad-ranging term which, amongst other things, encompasses the rules, relationships, policies, systems and processes whereby authority within organisations is exercised and maintained.<sup>1</sup>

An effective governance framework should have appropriate regard to the:

- contribution of individual directors;
- effectiveness of the board and board performance;
- financial performance and governance;
- ways in which governance is applied throughout the organisation; and
- strength of the relationships the organisation fosters with its stakeholders.

## 2. What is Clinical Governance?

Clinical governance is the set of relationships and responsibilities established by a health/aged care service organisation between its governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It ensures that community and health/aged care service organisations can be confident that systems are in place to deliver safe and high-quality care, and continuously improve services.<sup>2</sup>

Clinical governance includes:

- evidenced based models of care;
- clinical/care case management;
- ensuring that the organisation meets its duty of care to patients/residents;
- governance, leadership and culture to improve safety and quality;
- patient safety and quality improvement systems;
- appropriate clinical policies and procedures, including in relation to medication management and infection control;

- clinical performance and effectiveness, ensuring that the workforce has the right qualifications, skills and supervision to provide safe, high quality care to patients/residents/clients, together with clear responsibilities and accountability;
- a safe environment for the delivery of care;
- partnering with consumers in their own care including health literacy;
- a multi-disciplinary approach to and input into clinical policies and practice (including medical, nursing, mental health/dementia, geriatrics, palliative, pharmacy, dietician, allied health, social workers, etc.); and
- reporting, audit and accountability, for example, adverse events and incidents.

## 3. What is an Integrated Corporate and Clinical Governance Framework?

In organisations such as health and aged care providers (including hospitals) the Board is ultimately responsible for both corporate and clinical governance and both are equally important.

Directors and officers owe obligations under common law, and depending upon whether the company is 'for-profit' or 'not for profit' under the *Corporations Act 2001 (Cth)* and/or under the *Governance Standards of the Australian Charities and Not-for-profits Commission Act 2012 (Cth)*.

Foremost, the Board must lead by taking ultimate responsibility for clinical governance.<sup>3</sup> It is not appropriate for Boards to focus only on corporate management, whilst leaving clinical and care issues "up to the clinicians." There is a significant error in this thinking as demonstrated by the Oakden case described below. If the Board does not have the expertise, then the company should consider appointing independent director(s) with that expertise or obtain that expertise through a Board subcommittee or an advisory committee.

In many respects there is an overlap of corporate and clinical risks. A major clinical adverse event will have a negative impact upon the reputation and potentially the financial performance of the organisation.

An integrated corporate and clinical governance framework means that both corporate and clinical risks are reviewed in a holistic way including:

- a culture of compliance;
- setting the strategic direction for the organisation and its clinical/care services;
- ensuring the correct skill mix of the Board, including the appointment of independent directors with clinical skills as necessary;



<sup>1</sup> <http://aicd.companydirectors.com.au/resources/all-sectors/what-is-corporate-governance>

<sup>2</sup> *National Model Clinical Governance Framework* - Australian Commission on Safety and Quality in Health Care 2017, page 2.

<sup>3</sup> *The Board's Role in Clinical Governance*, Australian Institute of Company Directors 2011, page 16.



- appointment of appropriate Board sub-committees such as an audit and risk committee – independent of management – the role of audit and risk committees should include responsibility for both corporate/financial and clinical risks;
- board policies dealing with issues such as code of conduct, conflict of interest, delegation and confidential information;
- ensuring the responsibilities of managers for corporate and clinical responsibilities are clearly delineated so that there are no gaps and that they are clearly understood;
- involving stakeholders in decisions that affect them, including a consumer-driven model of care;<sup>4</sup>
- establishing sound audit and risk management practices and reporting (both corporate and clinical);
- monitor financial performance, reporting and compliance with standards;
- appropriate policies and procedures;
- legal and regulatory compliance as the sector is highly regulated, including in relation to accreditation, work health and safety and medications;
- appropriate skill mix and qualifications of managers and clinicians;
- orientation, training, continuing education and support, including education for the Board and managers; and
- ensuring that responsibilities are clearly understood and that managers are appropriately qualified and experienced; the implementation of a performance framework and accountabilities and ensuring that high standards of professional and ethical conduct are maintained.

<sup>4</sup> Adding Value to Governance in Aged Care, Governance Institute of Australia 2017

## 4. Why is Governance Relevant? – recent cases and lessons learnt

### 4.1 Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry

On 14 December 2017, the Governor-General of the Commonwealth of Australia, His Excellency General the Honourable Sir Peter Cosgrove AK MC (Retd) appointed former High Court Judge, the Honourable Kenneth Madison Hayne AC QC, to inquire into and report on misconduct in the banking, superannuation and financial services industry.

Some of the behaviours presented in the testimony of witnesses include:

- misleading regulators;
- charging people for products and services that they did not receive; and
- failing to compensate people in a timely manner.

The Royal Commission has raised serious governance issues.

A fundamental principle supporting governance is that Boards are accountable for the culture of their organisation and there would appear to have been significant cultural issues in terms of expectations of compliance.

Whilst banking, superannuation and finance is a different industry to the health and aged care sector, there are lessons to be learnt for every Board in Australia. A fundamental principle supporting governance is that Boards are accountable for the culture of their organisations, including accountability and transparency. Similar to banks, the health and aged care sector can greatly affect the lives of vulnerable consumers.

### 4.2 The Oakden Reports

In South Australia, there have been two investigations into systemic errors at the Oakden Older Persons Mental Health Service Review facility, which was a mental health facility and a residential aged care facility.

Oakden has resulted in two reports:

- *The Oakden Report – The Report of the Oakden Review* – Dr Aaron Groves, Chief Psychiatrist (April 2017)
- *Oakden, A Shameful Chapter in South Australia's History – A Report by the Hon Bruce Lander QC ICAC* (February 2018)

The Oakden Report (2018) indicated systemic errors involving: [at page 23]

- elder abuse, including the inappropriate use of excessive force and seclusion of consumers;
- the failure to report suspected misconduct;
- poor governance in respect of the use of nursing agency staff;
- inappropriate physical condition of facilities;
- alleged assault by staff on a consumer;
- alleged attempt by two nurses to catheterise a consumer with incorrect equipment and without consent;
- alleged failure of a nurse to follow up an invasive procedure that was performed without consent; and
- alleged persistent inappropriate behaviour by a nurse towards consumers.

Lessons to be learnt included [at page 15 of 2018 report] that the regime existed, (that enabled the Oakden Facility and its operators to deteriorate to such an extraordinarily poor state) for such an extended period of time without any meaningful intervention.

Closing the facility without fully and properly understanding how and why the facility and its operations could deteriorate to such an extent, seemingly unchecked, leaves open the very real possibility that similar failures could be perpetuated in the future in other settings.

The extent to which senior persons in positions of authority outside the Oakden Facility did not know about what was occurring at the facility was breathtaking.

Nobody had overall control over the facility. Nobody had full time responsibility solely for Oakden. It was an extraordinary management structure.

Recommendations included: [at page 16 of the 2018 report]

- (a) Consider adopting management structures for the administration of the *Mental Health Act 2009* (MHA) to match those of overall mental health clinical governance structures – eg an officer responsible for overseeing all clinical mental health care within a Local Health Network (LHN) as the responsibility for the administration of the MHA in that LHN
- (b) Implement a structure to routinely remind all staff working at a treatment centre, assign responsibilities at the centre and the expectations and responsibilities imposed on that staff member;
- (c) Chief Psychiatrist to have the power to conduct unannounced visits;
- (d) Reporting on condition of all facilities in which health services are delivered and to ensure that they are fit for the purpose for which they are being used;

- (e) New standards in relation to the use of restrictive practice and making the observance of those standards mandatory;
- (f) Adequate allied health staff to provide the necessary support at the facilities.

There was a significant failure of corporate and clinical governance illustrated by the Oakden Report. Senior people who were responsible by virtue of their office for the delivery of care and services to the consumers in the Oakden Facility, should have known what was going on.

### 4.3 Bergin Inquiry

On 12 February 2018, the NSW Government released the report of former NSW Supreme Court Justice Patricia Bergin, SC into the fundraising activities of RSL NSW, RSL Welfare and Benevolent Institution and RSL LifeCare (the **Company**).

The Honourable Bergin SC found that:

- the Company had not properly considered its obligations under Charitable Fundraising legislation;
- the Board had an obligation to have in place mechanisms that would assist the directors to recognise and deal with any conflicts of interest that arose;
- there was no advice given to either RSL NSW or RSL LifeCare for the need for ratification of the consulting fees by the members in general meeting; and
- RSL LifeCare did not obtain Ministerial approval for the remuneration or disclose same in its accounts, and its accounts did not comply with the requirements of the *Charitable Fundraising Act 1991* (NSW) (**Charitable Fundraising Act**)

A copy of the report is available at: <https://www.finance.nsw.gov.au/inquiry-under-charitable-fundraising-act-1991/>

All not-for-profit health and aged care providers who are registered as a charity with the Australian Charities and Not-for-profits Commission must ensure that they comply with the ACNC Governance Standards available at: [http://www.acnc.gov.au/ACNC/Manage/Governance/ACNC/Edu/GovStds\\_overview.aspx](http://www.acnc.gov.au/ACNC/Manage/Governance/ACNC/Edu/GovStds_overview.aspx)

Not all charities realise that fundraising is more than 'rattling the tin'. Charitable fundraising can involve raising funds through your website, through raffles or special events organised by the organisation with volunteers and residents.

If a charity has a charitable fundraising authority, then it must also comply with the relevant State/Territory charitable fundraising authority conditions. For example, in New South Wales there are special requirements for constitutions, dispute resolution, the financial accounts and auditing. Refer to: [http://www.fairtrading.nsw.gov.au/ftw/Cooperatives\\_and\\_associations/Charitable\\_fundraising/Fundraising\\_controls.page](http://www.fairtrading.nsw.gov.au/ftw/Cooperatives_and_associations/Charitable_fundraising/Fundraising_controls.page)

A Charitable Fundraising and Donations Policy and Charity Pack for staff and volunteers which complies with legal requirements is a recommended compliance tool.

The NSW Charitable Fundraising Act defines “fundraising appeal” broadly as follows:

- (1) For the purposes of this Act, the soliciting or receiving by any person of any money, property or other benefit constitutes a fundraising appeal if, before or in the course of any such soliciting or receiving, the person represents:
  - (a) that the purpose of that soliciting or receiving, or
  - (b) that the purpose of an activity or enterprise of which that soliciting or receiving is a part,is or includes a charitable purpose.
- (2) It does not matter whether the money or benefit concerned is solicited or received:
  - (a) in person or by other means (such as by post, telephone or facsimile transmission), or
  - (b) as a donation or otherwise (such as by participation in a lottery, art union or competition; by sponsorship in connection with a walkathon, telethon or other similar event; in connection with the supply of food, entertainment or other goods or services; or in connection with any other commercial undertaking).
- (3) The following do not, however, constitute a fundraising appeal for the purposes of this Act:
  - (a) a request for, or the receipt of, an amount required in good faith as the fee for renewal of membership of an organisation,
  - (b) an appeal by an organisation to (or the receipt of money or a benefit from) members of the organisation,
  - (c) a request that any property be devised or bequeathed, or the giving of any information as to the means by which any property may be devised or bequeathed,
  - (d) an appeal conducted exclusively or predominantly among persons sharing a common employer or place of work by one of those persons (being an appeal for a charitable purpose connected directly with another of those persons or any such other person’s immediate family) and the receipt of money or a benefit from any such appeal,
  - (e) an appeal to (or the receipt of money or a benefit from) any Commonwealth, State or local government authority,
  - (f) anything prescribed by the regulations.

## 5. Commentary

The common thread to all three of these recent cases was that:

- respective Boards did not necessarily understand the legal and compliance obligations of the organisation or did not implement them;
- that they failed to have a clear picture of what was actually going on inside their organisations; and
- the organisation did not have a culture of compliance.

So what is a culture of compliance and how can you test if you have one?

A culture of compliance is when everyone in the organisation from the Board down to all staff and volunteers embed compliance into their everyday workflow and the foundation and expectations for individual behaviour to comply is set across an organisation.

Alison Choy Flannigan has undertaken corporate and clinical governance reviews for many “for-profit” and “not-for-profit” clients and have sat on Risk Committees of major private and public hospital operators and other health organisations. She undertook a corporate and clinical governance review for RSL LifeCare in response to the Bergin Inquiry and her recommendations have been included in the Bergin Inquiry Report.

A version of this article was first published in *Governance Directions*, the official journal of Governance Institute. ■

## Personal Liability for Insolvent Trading: Company Directors Find Berth in Safe Harbour - Treasury Law Amendments (2017 Enterprise Incentive No 2)

By Shane Roberts, Partner and Sam Marsh, Solicitor

### Background

On 19 September 2017 the *Treasury Law Amendments (2017 Enterprise Incentive No 2) Act 2017* (the **Safe Harbour Reform Act**) came into effect.

The bill stated itself as amending the *Corporations Act 2001* to “create a safe harbour for company directors from personal liability for insolvent trading if the company is undertaking a restructure outside of formal insolvency [the safe harbour provisions]”.

### The safe harbour provisions

Australia’s insolvent trading regime means that directors risk being found personally liable for debts incurred if they allow their company to trade whilst insolvent. While this regime is intended to dissuade directors from allowing their companies to incur debts which they will be unable to repay, in application, the regime often has the perverse effect of inducing company directors to prematurely engage in the formal insolvency process when they could otherwise have successfully turned around their struggling company.

The intention of the proposals contained in the reform legislation was to encourage honest company directors to remain at the helm of a company facing financial difficulties and to take reasonable steps to restructure and allow it to trade out of its difficulties.

In fact, the Productivity Commission report provided to the government on 30 September 2015, and publicly released on 7 December 2015, stated: ‘A ‘safe harbour’ defence should be introduced to allow directors of a solvent company to explore, within guidelines, restructuring options without liability for insolvent trading.’<sup>5</sup>

The Safe Harbour Reform Act now legislates those intentions, with some key amendments having been made to the draft reform legislation as it passed through the Senate. This article discusses the effect of the amendments, and the practical application of the Safe Harbour Reform Act as passed.

### The effect: the safe harbour provisions

The Safe Harbour Reform Act provides that a director will no longer be personally liable for insolvent trading debts if, when they suspect the company is insolvent or likely to be insolvent, they develop one or more courses of action that are reasonably likely to lead to a better outcome for the company, as compared to the immediate appointment of an administrator or liquidator.

### Claiming a berth in the safe harbour

For a director to claim the protection provided by the Safe Harbour Reform Act, several factors must be considered to assess whether the course of action being developed was reasonably likely to lead to a better outcome.

Relevantly, this assessment will include consideration of some or all of the following questions:

1. Did the director take reasonable steps to keep themselves informed about the financial position of the company?
2. Did the director take reasonable steps to ensure that the company’s maintained appropriate financial records and met its reporting obligations, and were books and records handed over to any subsequent liquidator or administrator?
3. Did the director take reasonable steps to ensure that the company’s other officers and employees were not guilty of any misconduct or fraud?
4. Did the director ensure that the company paid all employee entitlements when due?
5. Did the director seek advice from an appropriately qualified professional?
6. Did the director heed any such advice, and did the director develop or implement a restructuring or turnaround plan for the improvement of the company’s financial position?

Therefore obtaining advice from an appropriately qualified professional and where appropriate, enacting that advice, remains a central pillar to utilising the safe harbour.

### ‘Developing’ a course of action

The Safe Harbour Reform Act provides that a director will be entitled to claim the protection of the safe harbour once he or she starts developing one or more courses of action (over a reasonable period) which are reasonably likely to lead to a better outcome.<sup>6</sup> This amends the Draft Reform Legislation, which proposed providing a safe harbour to a director only after they had actually commenced a particular course of action. The explanatory memorandum states: “*Developing requires more than merely thinking about the problem, but rather denotes actively taking steps to move towards a definite action.*”<sup>7</sup>

<sup>6</sup> Treasury Laws Amendment (2017 Enterprise Incentives No. 2) Act 2017, Schedule 1, Part 1, item 2, 588GA 1(a).

<sup>7</sup> Explanatory Memorandum, Treasury Laws Amendment (2017 Enterprise Incentives No 2) Bill 2017, para. 1.45.

<sup>5</sup> Productivity Commission, 2015, ‘Business Set-up, Transfer and Closure, Final Report’, 75 Canberra, p 2.





The Safe Harbour Reform Act appears to appreciate that generally directors will have a variety of potential turn around strategies which they could pursue, of which only some may be viable. The explanatory memorandum provides that a director who is genuinely intent on developing such a course of action will require a reasonable period of time to consider, and then enact, those options.<sup>8</sup>

## What is the 'reasonable period'?

Consideration of a 'reasonable period' is to be defined on a case-by-case basis, but it is important to note that dallying is not considered acceptable, and after due consideration of the available turn around strategies the director must ensure steps are swiftly taken that are reasonably likely to lead to a better outcome for the company.<sup>9</sup> Examples of a reasonable period given include a few days for a small simple company, to perhaps weeks or even months for larger, more complex, entities.<sup>10</sup>

This means that directors will now have a reasonable period of time to consider, develop and enact appropriate turnaround strategies instead of being bound to immediately take and implement one specific turnaround strategy. This is balanced by directors needing to act swiftly and decisively once they have decided upon the appropriate course of action.

## Temporal limits of the safe harbour

The Safe Harbour Reform Act provides that the safe harbour will be available from when the director suspects that their company is insolvent and starts to develop a course of action, and will

cease if the course of action is not enacted in a reasonable period of time (as above), where the director stops taking the course of action — or when the course of action ceases to be — reasonably likely to achieve a better outcome.

The draft reform legislation proposed that a director should only be able to claim a safe harbour up to the point that the company entered into receivership, or a scheme of arrangement. The Safe Harbour Reform Act rather provides that, in addition to the above, the safe harbour protections will continue up until the point when the company enters administration or liquidation.<sup>11</sup>

This means as the insolvency situation evolves and develops, the director must continuously ensure that the course of action will lead to a better outcome, and if not, change to another course of action which will do so — or place the company in the hands of an administrator or liquidator.<sup>12</sup> It also means that directors are afforded a reasonable period of time to develop and enact the turnaround strategy most appropriate in the circumstances, and to allow that course of action time to progress and to turn the company around and remove it from insolvency.

## How likely is 'reasonably likely'?

The explanatory memorandum provides that it is not necessary for 'reasonably likely' to mean the likelihood of achieving a better outcome is fifty percent or more, but instead that it must not merely be considered 'remote' or 'fanciful', and instead must be considered 'sufficient' or 'fair' (or more).<sup>13</sup>

<sup>8</sup> *Ibid*, para 1.44.

<sup>9</sup> *Ibid*, para 1.45.

<sup>10</sup> *Ibid*, para 1.46.

<sup>11</sup> Treasury Laws Amendment (2017 Enterprise Incentives No 2) Act 2017, Schedule 1, Part 1, item 2, 588GA (1)(b)(i)–(iv).

<sup>12</sup> Explanatory Memorandum, Explanatory Memorandum, Treasury Laws Amendment (2017 Enterprise Incentives No 2) Bill 2017, para 1.58.

<sup>13</sup> *Ibid*, para 1.52.



## What is a 'better outcome'?

The draft reform legislation proposed that directors could claim the protection of the safe harbour if they were following a course of action which would lead to a better outcome for both the company and its creditors. The Safe Harbour Reform Act removes the director's duty to the company's creditors, and imposes a duty from the director to the company only.

The explanatory memorandum states that this means that a director can now allow their company to incur debts to creditors associated with the sale of assets which would help the company's overall financial position.<sup>14</sup>

The draft reform legislation proposed that a 'better outcome' be defined in relation to the company becoming a Chapter 5 body corporate (for example, the company going into administration or being wound up) over some unspecified time period.

The Safe Harbour Reform Act now provides that a 'better outcome' is to be defined on a case-by-case basis 'depending on the individual company and its circumstances at the time the decision is made',<sup>15</sup> and that it is to be a better outcome as opposed to the immediate appointment of a liquidator or administrator over the company.

This means that the director will be able to ascertain with more certainty if the turnaround strategy being considered or taken will pass the 'better outcome' test, as they can now be sure of the specific threshold which must be passed to class the action as providing a better outcome.

## Who are 'appropriately qualified professionals'?

To utilise the safe harbour, a director should seek timely advice from an appropriately qualified professional. In assessing whether the insolvency professional is 'appropriately qualified', the explanatory memorandum states '[appropriately qualified professional] is used in the sense of 'fit for purpose' and is not limited merely to the possession of particular qualifications. It is for the person who appoints the adviser to determine whether the adviser is appropriate in the context'.<sup>16</sup>

The determination should have regard to the following:

- the nature, size, complexity and financial position of the business to be restructured;
- the adviser's independence, professional qualifications, good standing and membership of appropriate professional bodies (or in the case of an advising entity, those of its people);
- the adviser's experience; and
- whether the adviser has adequate levels of professional indemnity insurance to cover the advice being given.

<sup>14</sup> *Ibid*, para 1.49

<sup>15</sup> *Ibid*, para 1.18

<sup>16</sup> *Ibid*, para 1.69

The explanatory memorandum provides guidance and examples, such as a small business with a simple structure may require only the advice of an accountant, lawyer or other technical adviser with experience in insolvency.<sup>17</sup> A larger, more complex business may require the advice of a properly qualified, specialised insolvency or turnaround practitioner who is a member of a professional insolvency or turnaround association, or a specialist lawyer.<sup>18</sup> A very large complex business may need to retain an entire team of turnaround specialists, insolvency practitioners, and a law and accounting firm to advise on an appropriate course of action.<sup>19</sup>

This means that directors have the freedom to, and indeed must, ensure that the qualified professional has skills consummate with the case in hand.

## A carve-out rather than a defence and evidence

During the passage of the bill, amendments were tabled to enact the safe harbour provisions as a defence to insolvent trading in its own right, rather than to carve the insolvent trading provisions out of the existing legislation. These tabled amendments were not accepted, meaning the Safe Harbour Reform Act will provide directors with the safe harbour in the form of a carve out (that is, an exemption) of the insolvent trading provision contained in s 588G of the *Corporations Act 2001*, rather than as a stand-alone defence.

Therefore, a director who wishes to claim the safe harbour protection will merely have to adduce evidence which shows that the course of action was reasonably likely lead to a better outcome for the company and its creditors. Once this low evidential threshold is met, the onus of proof then shifts onto a liquidator to show, on the balance of probabilities, that the director did not develop a course of action reasonably likely to result in a better outcome for the company.<sup>20</sup>

## Scope of debts covered

The draft reform legislation proposed covering only those debts which were directly incurred as a part of the turnaround action, for example, only further loan agreements or credits taken after the commencement of the turnaround action.

The Safe Harbour Reform Act now provides protection for directors against direct and indirect debts incurred during the turnaround action, for example, debts incurred during the day-to-day running of the company.<sup>21</sup>

This means that directors cannot now be found personally liable for the ongoing debts of the company 'through the back door', as would have been the case under the draft reform legislation.

<sup>17</sup> *Ibid*, para 1.71

<sup>18</sup> *Ibid*, para 1.72

<sup>19</sup> *Ibid*, para 1.73

<sup>20</sup> *Ibid*, para 3.5

<sup>21</sup> Treasury Laws Amendment (2017 Enterprise Incentives No 2) Act 2017, Schedule 1, Part 1, item 2, 588GA (1)(b)



## Two-year review

The Safe Harbour Reform Act provides that it will be reviewed as soon as practicable two years from the date of commencement, being July 2019.

This means further amendments to the Safe Harbour Reform Act may be made in two years or more based upon the evidence and experience from the enacting of the Safe Harbour Reform Act. This review will consider the application and effect of the Safe Harbour Reform Act on companies, directors, and the interests of employees, and creditors.<sup>22</sup>



## Conclusion

The enactment of the Safe Harbour Reform Act represents a steep change in the manner in which directors are able to address issues of their company's solvency.

Directors are now afforded additional protection to allow them the time and support necessary to turnaround a struggling company. The safe harbour protection comes with limits, and it is incumbent on directors to know how the new regime will affect them and their company during periods where solvency is in question.

The director can be reassured that they are protected by the safe harbour so long as they follow the correct procedures, including developing a sound turnaround plan, often with the advice of an appropriately qualified professional, and that they continued to evaluate that plan and changed tack where necessary.

This article was first published in *Governance Directions*, the official journal of Governance Institute. ■

<sup>22</sup> *Ibid* item 3, 588HA

## Aged Care Quality Reforms Aged Care (Single Quality Framework) Reform Bill 2018 (Cth)

By Alison Choy Flannigan, Partner and Rui Chi, Solicitor

### Review of National Aged Care Quality Regulatory Processes

An independent review of the National Aged Care Quality Regulatory Processes (the **Review**) was announced in response to the Oakden Report which detailed failures in the quality of care delivered at the Oakden Older Persons Mental Health Service in Australia.<sup>23</sup>

Following the publication of the Report into the Review of the National Aged Care Quality Regulatory Processes on 25 October 2017, which was led by Ms Kate Carnell AO in conjunction with Professor Ron Paterson, the Minister of Aged Care, Ken Wyatt announced several significant reforms to take place in the aged care community.<sup>24</sup>

The key impending changes are:

- the establishment of a new Independent Aged Care Quality and Safety Commission (**Commission**) from 1 January 2019 to centralise accreditation, compliance and complaints handling;
- enhanced risk profiling of aged care providers to determine the frequency and rigour of visits;
- the development of options, in consultation with the sector, for an efficient Serious Incident Response Scheme to ensure the right systems are in place to identify and prevent situations such as Oakden from occurring again;
- the introduction of a performance rating against the quality standards; and
- the development of a user-friendly provider comparison tool on the My Aged Care Website.

### Improving effectiveness of accreditation and unannounced audits

To strengthen ongoing accreditation processes, all residential care services will be subject to unannounced re-accreditation audits for those services:

- applying for re-accreditation from 1 July 2018; and
- with an accreditation expiry date on or after 1 January 2019.

<sup>23</sup> Refer to the article on the Oakden Report in this publication.

<sup>24</sup> Review of National Aged Care Quality Regulatory Processes, Department of Health: <https://agedcare.health.gov.au/quality/review-of-national-aged-care-quality-regulatory-processes>.

Services that have already been advised of the date of their re-accreditation site audit or facilities with an accreditation expiry date before 1 January 2019 will not be affected by this change.

The unannounced re-accreditation audits are intended to capture a provider's everyday performance against Accreditation Standards.

For the transition into a more responsive regulatory model, the expanded risk profiling of providers will be applied to determine the frequency and duration of unannounced visits commensurate with providers with the greatest risk of non-compliance.

## A new national independent oversight body

Higher quality benchmarks will be established in the aged care system to give assurance to the senior Australians and their families that they will be properly cared for through a new and independent Aged Care Quality and Safety Commission. The Commission will streamline the functions of the Australian Aged Care Quality Agency, the Aged Care Complaints Commissioner and the aged care regulatory functions of the Department of Health.

The new Commission is anticipated to be a responsive avenue to address any quality issues that may arise within the system.

The unified Commission seeks to ensure that the risks to senior Australians and care failures within the aged care system will be identified, alleviated and rectified quicker than before. It is also anticipated that the new integrated agency will provide senior Australians with more transparency when choosing aged care options.

The Commission will be led by an Independent Aged Care Quality and Safety Commissioner who will report to the Minister of Aged Care and be supported by an advisory group and a new Chief Clinical Advisor.

## Improved response to serious incidents of abuse and neglect

In the recognition of better safeguard for consumer's rights, a new independent Serious Independent Response Scheme (SIRS) will be enacted for aged care with oversight from the new Aged Care Commissioner. The SIRS should replace the current reportable assaults process in the *Aged Care Act 1997*.

Under the new scheme, aged care providers should give the Aged Care Commissioner notice as soon as possible or within 28 days of becoming aware of a reportable incident. The incident will be investigated and an appropriate action to be determined by the Aged Care Commissioner.

To enhance the transparency and accountability of providers in handling complaints, the Review also recommended that providers be obliged to report the number of incidents and the Aged Care Commissioner will be empowered to publicly name providers who create barriers to legitimate complaints handling as non-compliant providers.

## Star-rated system for provider performance reporting

To provide accessibility of information to consumers on quality of care, a star-rated reporting system for performance data will be introduced. The proposed new performance reporting system will encapsulate the results from accreditation audits and consumer experience reports. The scores against each Accreditation Standard, including an overall score for each facility, will also be provided to the consumer.

Accompanying the star-rated reporting system, the new Aged Care Commissioner will also make available an online comparison tool to allow consumers to easily compare the performance of aged care homes in a chosen area.

## Improved assessment against Accreditation Standards

One of the concerns raised in the Review is the lack of clarity around best practice for clinical care, particularly issues relating to the administration of medication, sterilisation standards and incident reporting protocols.

## Single Quality Framework

The Government has also introduced the *Aged Care (Single Quality Framework) Reform Bill 2018 (Cth)* which is intended to come into force from 1 July 2019, giving a 12 month transition period to allow for any system and process changes required to meet the new standards. The Bill amends the *Aged Care Act 1997 (Cth)* and the *Australian Aged Care Quality Agency Act 2013 (Cth)*.

The proposed Aged Care Quality Standards implemented under the Bill will replace the existing quality standards including:

- accreditation standards for residential care;
- home care standards for home care; and
- flexible care standards for short-term restorative care.

The Aged Care Quality Standards will be more focused on consumers rather than provider processes. It is anticipated that the standards will improve the quality of care delivered to consumers, enable a competitive system driven by consumer standards, and thereby decrease regulatory burden on aged care providers.

The *Freedom of Information Act 1982* will also be amended so that documents containing protected information acquired by the Commission in the course of its functions are exempt from disclosure.

## Aged Care Quality Standards

In March 2017, the Department of Health (the **Department**) released two consultation papers seeking stakeholder feedback on key elements of a proposed new Single Quality Framework for aged care. The consultation papers sought stakeholder views about:

- the draft quality standards described in the Single Aged Care Quality Framework – Draft Quality Standards Consultation Paper 2017 (the **Draft Quality Standards Consultation Paper**)
- options for improving the processes for assessing performance against the single set of quality standards described in Single Aged Care Quality Framework – Options for Assessing Performance against Aged Care Quality Standards – Options Paper 2017 (the **Assessment Options Paper**)

The current draft sets out the following eight standards:

## *Standard 1 – Consumer dignity and choice*

### Consumer outcome

I am treated with dignity and respect, and can maintain my identity. I can make informed choices about my care and services, and live the life I choose.

### Organisation statement

The organisation:

- Has a culture of inclusion and respect for consumers
- Supports consumers to exercise choice and independence
- Respects consumers' privacy.

### Requirements

The organisation demonstrates the following:

- 1.1 Each consumer is treated with dignity and respect, and their identity, culture and diversity is valued.
- 1.2 Each consumer is able to (and supported to as needed) exercise choice and independence, including to:
  - make decisions about their own care and the way that care and services are delivered
  - make decisions about when family, friends, carers or others should be involved in their care
  - communicate their decisions
  - make connections with others and maintain relationships of choice, including intimate relationships.
- 1.3 Where a consumer's choice involves risk to their health and/or safety, they are informed about the risks, the potential consequences to themselves and others, and how risk can be managed to assist the consumers to live the life they choose.
- 1.4 Information provided to each consumer is current, accurate and timely, and communicated in a way that supports the consumer's understanding and the exercise of choice.

- 1.5 Each consumer's personal privacy is respected and information is kept confidential.

## *Standard 2 – Ongoing assessment and planning with consumers*

### Consumer outcome

I am a partner in ongoing assessment and planning that helps me get the care and services I need for my health and wellbeing.

### Organisation statement

The organisation undertakes initial and ongoing assessment and planning for care and services in partnership with the consumer. Assessment and planning has a focus on optimising health and wellbeing in accordance with the consumer's needs, goals and preferences.

### Requirements

The organisation demonstrates the following:

- 2.1 Ongoing partnership with the consumer (and others that they wish to involve) in assessment, planning and review of their care and services.
- 2.2 Assessment and planning informs the delivery of safe and effective care and services.
- 2.3 Assessment and planning identifies and addresses the consumer's current needs, goals and preferences, including advance care planning and end of life planning if the consumer wishes.
- 2.4 The assessment and planning process is undertaken in a culturally safe manner.
- 2.5 The assessment and planning process includes other providers, organisations and individuals involved in the care of the consumer.
- 2.6 The outcomes of assessment and planning are effectively communicated to the consumer and documented in a care and services plan that is readily available to the consumer, and where care and services are provided.
- 2.7 Care and services are reviewed regularly for effectiveness, and when circumstances change or when incidents impact on the needs, goals or preferences of the consumer.

## *Standard 3 – Personal care and clinical care*

### Consumer outcome

I get personal care and/or clinical care that is safe and right for me.

### Organisation statement

Personal care and clinical care is safe and effective and delivered in accordance with the consumer's needs, goals and preferences to optimise health and wellbeing.



## Requirements

The organisation demonstrates the following:

- 3.1 Each consumer gets safe and effective personal care and/or clinical care that is tailored to their needs and optimises their health and wellbeing.
- 3.2 Clinical care is best practice.
- 3.3 Identification and management of high-impact or high-prevalence risks associated with the care of each consumer.
- 3.4 The needs, goals and preferences of consumers nearing the end of life are recognised and addressed, their comfort maximised and their dignity preserved.
- 3.5 Deterioration or change of a consumer's function, capacity or condition is recognised and responded to in a timely manner.
- 3.6 Information about the consumer's condition, needs and preferences is documented and communicated within the organisation, and with others where responsibility for care is shared.

3.7 Timely referrals to other providers, organisations and individuals when necessary.

3.8 Minimisation of infection-related risks to consumers, the workforce and the broader community through implementing:

- standard and transmission-based precautions to prevent and control infection
- practices to promote appropriate antibiotic prescribing and use to support optimal care and reduce the risk of increasing resistance to antibiotics.

*Standard 4 – Services and supports for daily living\**

## Consumer outcome

I get the services and supports that are important for my health and wellbeing and that enable me to do the things I want to do.

## Organisation statement

The organisation provides safe and effective services and supports that optimise the consumer's independence, health, wellbeing and quality of life.

## Requirements

The organisation demonstrates the following:

- 4.1 Each consumer gets safe and effective services and supports for daily living that are culturally safe and meet the consumer's needs, goals and preferences and optimise their independence, health, wellbeing and quality of life.
- 4.2 Services and supports for daily living support each consumer to participate in their community within and outside the service, have social and personal relationships, and do the things of interest to them.
- 4.3 Information about the consumer's condition, needs and preferences is documented and communicated within the organisation, and with others where responsibility for care is shared.
- 4.4 Timely referrals to other providers, organisations and individuals when necessary.
- 4.5 Where meals are provided, they are varied and of adequate quality and quantity.

\*Services and supports for living include, but are not limited to, food services, domestic assistance, home maintenance, transport, recreational and social activities.

## *Standard 5 – Organisation's service environment\**

### Consumer outcome

I feel I belong and I am safe and comfortable in the organisation's service environment.

### Organisation statement

The organisation provides a safe and comfortable service environment that promotes the consumer's independence, function and enjoyment.

### Requirements

The organisation demonstrates the following:

- 5.1 A service environment that is welcoming and easy to understand, and optimises each consumer's sense of belonging, independence, interaction and function.
- 5.2 A service environment that is safe, clean, well-maintained and comfortable, including furniture and equipment that is suitable for the consumer.
- 5.3 Consumers can move freely within the service environment, including both indoor and outdoor areas.

\*An organisation's service environment refers to the physical environment through which care and services are delivered, including aged care homes, cottage style respite services and day centres. An organisation's service environment does not include a person's privately owned/occupied home through which in-home services are provided.

## *Standard 6 – Feedback and complaints*

### Consumer outcome

I feel safe and am encouraged and supported to give feedback and make complaints. I am engaged in processes to address my feedback and complaints, and appropriate action is taken.

### Organisation statement

Regular input and feedback from consumers, carers, the workforce and others is sought and is used to inform individual and organisation-wide continuous improvements.

### Requirements

The organisation demonstrates the following:

- 6.1 Consumers, their family, friends, carers, and others are encouraged and supported to provide feedback and make complaints.
- 6.2 Regular feedback is sought from consumers, carers, the workforce and others about their experiences of the service.
- 6.3 Consumers have access to advocates, language services and other mechanisms for raising and resolving complaints.
- 6.4 An open disclosure process is used in resolving complaints and when things go wrong.
- 6.5 Feedback and complaints are examined and used to improve the quality of care and services.

## *Standard 7 – Human resources*

### Consumer outcome

I get quality care and services when I need them from people who are knowledgeable, capable and caring.

### Organisation statement

The organisation has sufficient skilled and qualified workforce to provide safe, respectful and quality care and services.

### Requirements

The organisation demonstrates the following:

- 7.1 The workforce is planned and the number and mix of staff deployed enables the delivery and management of safe and quality care and services.
- 7.2 The workforce behaves and interacts with each consumer in a way that is caring and respectful, and embraces their identity, culture and diversity.
- 7.3 The workforce has the skills, capabilities, qualification and knowledge to effectively perform their role.
- 7.4 The workforce is recruited, trained, equipped and supported to deliver the outcomes required by these standards.

7.5 Regular assessment, monitoring and review of the performance of each member of the workforce.

## Standard 8 – Organisational governance

### Consumer outcome

I am confident the organisation is well run. I am a partner in improving the delivery of care and services.

### Organisation statement

The governing body is accountable for safe and quality care and services.

### Requirements

The organisation demonstrates the following:

8.1 Partnering with consumers in the planning, delivery and evaluation of care and services (including supporting consumers to do so).

8.2 The organisation's governing body promotes a culture of safe, inclusive and quality care and services and is accountable for their delivery.

8.3 Effective governance supported by organisation wide systems for safety and quality, including systems for:

- continuously improving outcomes for consumers
- risk management, including managing high impact or high prevalence risks associated with the care of consumers
- information management
- practising open disclosure
- ensuring clear responsibilities and accountabilities
- ensuring compliance with legislative requirements and relevant standards
- antimicrobial stewardship
- identifying and responding to abuse and neglect of consumers
- minimising the use of physical and chemical restraint.

8.4 When clinical care is delivered, an effective clinical governance framework is established and maintained as an integral part of the organisation's governance

A copy of the draft Aged Care Quality Standards is available at: <https://agedcare.health.gov.au/quality/single-set-of-aged-care-quality-standards/draft-aged-care-quality-standards-and-draft-application-of-draft-aged-care-quality-standards-by-service-type>

The final standards will be presented to government for consideration. Subject to the agreement of the Australian Government and any necessary amendments being made to legislation, the new standards will take effect from 1 July 2018.

All Approved Providers should have reviewed their policies and procedures to be consistent with the proposed new standards.

## Enhanced information on quality of services

More information on the quality of both residential and community aged care services will help consumers to make informed decisions about their care and services.<sup>25</sup>

Enhancements to improve access to quality information on the My Aged Care website include:

- improvements to the home care packages service finder, enabling providers to advertise detailed information about their costs and the addition of search fields such as: religion, language, special needs and specialised services;
- a 'non-compliance service finder' to allow consumers to more easily search for current and archived compliance action taken against residential services and home care package providers;
- information about how to find quality services, and how consumers' rights are protected;
- information about a residential aged care service's accreditation status with improved links to the Australian Aged Care Quality Agency 's accreditation audit reports and consumer experience reports, where available; and
- an icon in the service finder identifying a provider's participation in the voluntary National Quality Indicator Program (NQIP) for residential aged care providers. ■

<sup>25</sup> <https://agedcare.health.gov.au/quality/single-quality-framework-focus-on-consumers>



## Exclusion Zones for Reproductive Health Facilities in NSW - Public Health Amendment (Safe Access to Reproductive Health Clinics) Act 2018 (NSW)

By Alison Choy Flannigan, Partner and Sarah Spear, Associate

The *Public Health Amendment (Safe Access to Reproductive Health Clinics) Act 2018 (NSW)* was passed on 7 June 2018. The Act commences on the date of assent which is yet to be announced. The Act amends the *Public Health Act 2010 (NSW)*.

Similar legislation already exists in:

- ACT – *Health Act 1993 (ACT)*;
- Victoria - *the Public Health and Wellbeing Act 2008 (Vic)*; and
- Tasmania – *Reproductive Health (Access to Terminations) Act 2013 (Tas)*.

The Act establishes a 150m “safe access zone”.

A “safe access zone” means:

- (a) the premises of a reproductive health clinic at which abortions are provided; and
- (b) the area within 150 metres of:
  - a. any part of the premises of a reproductive health clinic at which abortions are provided; or
  - b. a pedestrian access point of a building that houses a reproductive health clinic at which abortions are provided.

A “reproductive health clinic” means any premises *at which medical services relating to aspects of human reproduction or maternal health are provided, but does not include a pharmacy*” (s98A).

Prohibited interference within the safe access zone will include:

- to harass, intimidate, beset, threaten, hinder, obstruct or impede by any means (s98C(1));
- to interfere with any person accessing, leaving, or attempting to access or leave, any reproductive health clinic at which abortions are provided (s98C(2));
- if a person is in a safe access zone, to, without reasonable excuse, obstruct or block a footpath or road leading to any reproductive health clinic at which abortions are provided. (s98B(3)); and
- making a communication that relates to abortions, by any means, in a manner:

- that is able to be seen or heard by a person accessing, leaving, attempting to access or leave, or inside, a reproductive health clinic at which abortions are provided; and
- that is reasonably likely to cause distress or anxiety to any such person (s 98D).

However, section 98D does not apply to a person who provides services at a reproductive health clinic. (s98D(1)(a));

- intentionally capturing visual data of another person, by any means, without consent if that person is in a safe access zone (s 98E). The publication and distribution of such visual data is listed as a separate offence (s98E(2)). Section 98E does not apply to the operation of a security camera by the operator of the clinic or premises adjacent or near, people employed or contracted to the clinic, or the police or another person who has another reasonable excuse.

Penalties for all of the above are capped at 50 penalty units or imprisonment for 6 months (or both) for a first offence, and 100 penalty units or imprisonment for 12 months for second and further offences.

There are exemptions to the prohibitions within safe access zones including for conduct within the grounds of a church or other building that is ordinarily used for religious worship (s98F(1)(a)).

As NSW attempts to legislate for safe access zones, the existing regimes in both Victoria and Tasmania are currently facing High Court challenges.

In the Victorian case, *Edwards v Clubb (unreported, Magistrates Court of Victoria 11 October 2017, Case G12298656)* Kathleen Clubb, a member of a group called the “Helpers of God’s Precious Infants”, became the first person found guilty of an offence under the *Public Health and Wellbeing Act* after attempting to hand a pamphlet about abortion to a couple within the safe access zone of the East Melbourne Fertility Clinic. According to the submissions of the First Respondent in the case, the group provided notice to Victoria Police that they would be breaching the safe access zone on the date of the offence in order to “test the validity of the legislation.” (Submissions – First Respondent, 5.5, 18 May 2018) Clubb is appealing the \$5,000 fine and good behaviour bond for 2 years (with conviction), and the matter is currently before the High Court (*Clubb v. Edwards & Anor M46/2018*). The Constitutionality of the restrictions on communication in safe access zone was considered at first instance, and the appeal is based on a perceived denial of the freedom of political communication of Ms Clubb.

Submissions from the Victorian Attorney General on this issue have focused on whether the direct communication to those seeking an abortion, within the safe zone, can be seen to be political, or whether it is effectively an interference into a personal and private matter. The State argues that not all communications about abortion are political; for a communication to be “political”, it must be intended to persuade the public, or a sector of the public to a particular view. Whilst the AG agrees that “some individuals might be engaging in political communication, in other cases the aim is to deter women from having an abortion, often through imposing guilt and shame”. (Submissions – para. 31 Attorney General of Victoria, 11 May 2018)





On 25 May 2018, the Attorneys General for the Commonwealth, NSW, QLD, WA and SA all provided written submissions to intervene in the Clubb matter before the High Court. At the same time, the Human Rights Law Centre, the Castan Centre for Human Rights Law have also sought leave to be considered amicus curiae (as an advisor to the Court), and the Fertility Control Clinic (within the safe access zone in which the arrest was made in East Melbourne), have sought to either intervene or be considered amicus.

Discussion and debate about abortion - its methods, risks, morality, ethics, rights, dangers, alternatives and any other aspect can be the subject of authentic political communication – however, none of these are able to be undertaken within the safe access zones. The freedom of political communication is not a right to confront women making personal, and not political, decisions. “The implied freedom does not guarantee a right to a captive audience” (Submissions – para 45 Attorney General of Victoria, 11 May 2018)

The Tasmanian appeal (*Preston v Avery & Anor* [H2/2018]) is made on similar facts, under the Tasmanian legislation *Reproductive Health (Access to Termination) Act 2013 (Tas)*, with submissions not yet due in that matter.

It remains to be seen whether a similar test-case scenario will be enacted in New South Wales. ■



## Establishment of the NDIS Quality and Safeguards Commission

By Alison Choy Flannigan, Partner

The *National Disability Insurance Scheme Amendment (Quality and Safeguards Commission and Other Measures) Act 2017* (the **NDIS Commission Act**), amending the *National Disability Insurance Scheme Act 2013* will come into force in Australia on 1 July 2018.<sup>26</sup>

The NDIS Commission Act will allow the establishment of the NDIS Quality and Safeguards Commission (the **NDIS Commission**), who will implement the NDIS Quality and Safeguarding Framework, which will be embedded as the national support system for NDIS participants, carers and providers and their staff. As the disability support sector moves from State-by-State implementation to a full national system, the importance of having consistent cross-border standards for rights, responsibilities, levels of care, safeguards and expectations for all participants has been realised.

The NDIS Commission has been funded in the 2018 Federal Budget in the amount of \$209 million, and will be established as an independent body, regulating providers, handling quality and safety complaints, and work for nationally consistent standards of care and support.

The Commissioner will assume responsibility for NDIS management in NSW and SA on 1 July 2018; on 1 July 2019 for Victoria, QLD, Tasmania, ACT and the NT; and finally on 1 July 2020 for WA.

The new NDIS Commission will oversee a stratification of NDIS provider registration: providers that deliver lower risk, less complex supports and services will undergo a **Verification** assessment, whilst providers delivering higher risk and complex supports and services will undergo a **Certification** assessment. Regardless of assessment level, all providers of NDIS Services will be required to comply with the NDIS Code of Conduct.

The registration of existing service providers will automatically transfer to the NDIS Commission.



### Obligations on providers



Unregistered providers	Registered providers (lower risk)	Registered providers (higher risk)
NDIS Code of Conduct		
Complaints process		
Voluntary Worker Screening	Mandatory Worker Screening	
Reportable Incident requirements		
Practice Standards verification	Practice Standards certification	Restrictive Practice reporting (if applicable)

<sup>26</sup> The source of this article is the powerpoint presentation of the NDIS Quality and Safeguard Commission - NDIS National Provider Forum 2018.

## Queensland Retirement Village Reforms - Housing Legislation (Building Better Futures) Amendment Act 2017 (Qld)

By Alison Choy Flannigan, Partner

The *Housing Legislation (Building Better Futures) Amendment Act 2017 (Qld)* was passed by Parliament on 25 October 2017 and assented to on 10 November 2017. Part 7 contains amendments to the *Retirement Villages Act 1999 (Qld)* (**Act**).<sup>27</sup>

The changes to the Act will increase transparency in the relationships between retirement village operators and residents, and will provide additional security and confidence to residents.

### What will change

- Behavioural standards that guide how village operators, staff and residents interact with each other have been introduced. These standards ensure respect for the rights and obligations of all parties and the quality of life of residents.
- An operator must pay the exit entitlement of a former resident at 18 months if their unit is not sold. For residents who have already left their retirement village and whose unit has not sold, the 18-month period started on 10 November 2017. An operator may apply to Queensland Civil and Administrative Tribunal (**QCAT**) if paying the exit entitlement will cause them undue financial hardship. QCAT will consider the matter and may determine a later payment date or payments by instalment.

The following changes will be implemented at a later date, to be advised. These changes will support prospective residents by:

- improving pre-contractual disclosure to allow prospective residents to compare retirement villages and other options so they understand the costs of entering, living in, and leaving a village
- allowing for simpler, standardised contracts; and
- allowing them 21 days to review their contract and seek financial and legal advice before they sign.

Operators will be required to provide a “village comparison document” (section 74) in the approved form which will give general information about a retirement village scheme to potential residents of the retirement village, including information about available types of accommodation, facilities and services and amounts payable by or to residents, the scheme operator and other persons. In addition, operators will be required to provide a “prospective costs document” (section 75) to give to a prospective resident of a retirement village a summary of the estimated costs of moving into, living in and leaving the retirement village.

The following changes will also be implemented at a later date, to be advised. These changes will protect residents.

- New requirements for operators to prepare and obtain approval for plans for proposed changes in village operations, such as closure, redevelopment, or change in operator.
- Improved financial transparency regarding retirement village funds, budgets and financial statements.
- A fairer process for identifying work needed to refurbish and reinstate units when a resident decides to leave. This process will distinguish between reinstatement and refurbishment works, and clarify who is responsible for the costs of each.

### Implementation

The Government is currently working with the community and industry to finalise the detail of these changes. A timeline has been released which details the program of works required to change the legislation.



Activity	May 2018	June 2018	July 2018	Aug 2018	Sept 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019
<b>Retirement Villages Act 1999</b>																
Consultation – Stage 1																
• Pre-contractual disclosure																
• Access to documents																
• Reinstatement of unit																
Implementation – Stage 1																
Consultation – Stage 2																
• Change in village operations																
• Retirement village contracts																
Implementation – Stage 2																
Consultation – Stage 3																
• Standard financial reports and budgets																

<sup>27</sup> Source: <http://www.hpw.qld.gov.au/Housing/IndustryRegulation/RetirementVillages/Pages/Retirement%20villages.aspx>; *Housing Legislation (Building Better Futures) Amendment Act 2017 (Qld)*



## What is Competent Professional Practice – *Sparks v Hobson; Gray v Hobson [2018] NSWCA 29*

by Zara Officer, Special Counsel

The recent decision of the NSW Supreme Court, Court of Appeal in *Sparks v Hobson; Gray v Hobson [2018] NSWCA 29* raises a number of issues relating to the interpretation of the provisions of the *Civil Liability Act 2002 (NSW)* as they relate to medical negligence cases. Uncertainty is introduced by the differing judgments of the three Court of Appeal justices who decided this case, and it is currently the subject of a special leave application in the High Court.

The case provides an example of where unchallenged supportive peer professional evidence did not protect one of the defendants, a specialist anaesthetist, from a finding of breach of duty.

### Relevant provisions

Under s 50 of the *Civil Liability Act 2002 (NSW)* (the **Act**) a professional will not be liable “if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice”. This section is widely applied as a defence available to a professional who is defending a negligence claim. In medical negligence cases, both parties call expert evidence to attempt to demonstrate that what the defendant did either fell short of, or did not fall short of, acceptable professional practice.<sup>28</sup>

Under s 51 of the Act, “a person is not liable in negligence for harm suffered by another person as a result of the materialisation of an inherent risk”. Inherent risk is “something occurring that cannot be avoided by the exercise of reasonable care and skill”.

Both of these sections were relevant to the findings in Mr Hobson’s case.

### The facts

Mr Hobson was born with Noonan Syndrome, a feature of which was a serious curvature of his spine resulting in reduced chest cavity, particularly on the left side. Mr Hobson suffered increasing breathlessness and a pattern of restrictive airways disease.

Corrective surgery involved a two stage operation intending to relieve the pressure on the chest cavity by strengthening the spine. The first stage was completed uneventfully. The second stage was scheduled for 10 days later, but because pneumonia developed in Mr Hobson’s left lung it was performed urgently 4 days after the first surgery, in life saving circumstances.

The second surgery required Mr Hobson to be placed face down whilst screws were inserted into his spine. This position created further pressure on his chest, increasing restrictions on his breathing, and the procedure was terminated early. Mr Hobson was left a paraplegic due to a severe ischemic collapse in his spinal column during the operation. The operation was, at a later time, completed successfully but Mr Hobson did not recover the use of his lower limbs.

The trial judge found that the operation should have been stopped 15 minutes earlier than it was, and he found both the anaesthetist, Dr Sparks and the surgeon, Dr Gray liable. On appeal, Dr Gray, the surgeon, was unanimously found not liable, but breach of duty was established in relation to the anaesthetist Dr Sparks by a majority of 2:1.

### The judgments

Based on different reasoning, Justices Macfarlan and Basten considered Dr Sparks’ decision to allow the operation to continue for so long was a breach of his duty of care to Mr Hobson. Justice Simpson did not conclude that the evidence established that the failure by Dr Sparks to terminate the operation earlier amounted to a departure from the standard of reasonable care and skill required of a specialist anaesthetist.

Justice Basten:

- considered the continuation of the operation involved a failure to exercise reasonable care and skill by Dr Sparks, who was responsible, amongst other matters, for monitoring blood pressure, oxygen and CO<sub>2</sub> levels in the blood. Therefore he found a breach of duty by Dr Sparks;
- concluded that the expert evidence, while it supported Dr Sparks, did not squarely address what became the critical issue, which was whether the failure to terminate the operation at an earlier point satisfied the test of whether Dr Sparks acted in a manner widely accepted in Australia as competent professional practice;
- interpreted s 50 as relevant to establishing the standard of care relevant to assessing breach of duty, rather than a defence to be addressed after findings were made in the plaintiffs case;
- rejected the suggestion that the defence in s 50 of the *Civil Liability Act* only applies where the defendant can identify a regular course of conduct adopted in particular circumstances; and
- did not consider s 51 of the Act relevant to inherent risk applied in the circumstances.

<sup>28</sup> *Dobler v Halverson* (2007) 70 NSWLR 151.

Justice Macfarlan:

- considered that in order to establish that a practitioner has acted in accordance with the professional standard, they must demonstrate that they conformed with “a practice” in the sense of a pattern of response by medical practitioners to a clinical scenario, as opposed simply to a widespread view among peers that what the defendant did in the circumstances constituted competent professional practice;<sup>29</sup>
- did not consider it was sufficient that the experts called to give evidence agreed that the conduct was reasonable, and that it would have been regarded as reasonable by other professionals if they had been asked about it at the time of the conduct. Because the experts did not point to an established practice that was followed by Dr Sparks in the circumstances of Mr Hobson’s operation, Dr Sparks was unable to rely on the defence in s 50 of the *Civil Liability Act*; and
- did not think s 51 of the Act on inherent risk applied in the circumstances.

Justice Simpson:

- felt constrained by precedent to adopt the approach of Macfarlan JA because of the decision in the *McKenna v Hunter & New England Local Health District*. [2013] NSWCA 476 case. However, Simpson JA did not agree with a construction of s 50 as applying only in limited circumstances where a defendant identifies a discrete practice to which he or she conforms. She noted that this necessarily excludes unusual factual circumstances and she did not consider that s 50 was intended to have such limited application. Reluctantly Simpson JA considered Dr Sparks failed to establish a defence based on s 50 because he could not identify a practice to which he conformed, notwithstanding that the expert witnesses agreed that Dr Sparks acted reasonably in the actions he took during the operation, and they considered professional peers would likely have taken the same view;
- nevertheless found in favour of Dr Sparks under s 51 of the Act on the basis that Mr Hobson’s injuries were the materialisation of an inherent risk that could not be avoided by the exercise of reasonable care and skill; and
- found that Dr Sparks did not fail to exercise reasonable care and skill, so there was no breach of duty. The overwhelming medical evidence was that Dr Sparks conduct was in accordance with what was widely accepted in Australia as competent professional practice. She noted the only way the court could reach a conclusion about whether Dr Sparks met the standard of the ordinary skilled anaesthetist is when the court is informed by the evidence of witnesses with appropriate expertise.



## Comment

It is hoped that the High Court will grant special leave to Dr Sparks to conduct an appeal so that the interpretation of s 50 can be clarified. The difficulty with the need to establish a “practice” as suggested by Macfarlan JA is that in an unusual case such as this one, there may be no relevant practice in existence that the defendant doctor can identify.

This article has not focussed on s 51, but the case raises questions of when the materialisation of an inherent risk provision in the Act will be applied in medical negligence cases.

The case draws attention to the differing approaches to the application of s 50, both as a defence, with the onus of proof lying on the defendant, and its central role in the primary finding on liability as to what standard of care is to be applied when assessing the alleged negligence, with the onus of proof lying also on the plaintiff.

The judgments in Mr Hobson’s case appear irreconcilable and have created uncertainties which only the High Court can resolve. ■

<sup>29</sup> In this Macfarlan JA followed his earlier approach in *McKenna v Hunter & New England Local Health District* [2013] NSWCA 476. Basten JA did not consider the *McKenna* case was binding as it had been overturned by the High Court (although not on the issue of the s 50 defence).



## Therapeutic Goods Advertising Code 2018 Update

By Alison Choy Flannigan, Partner

Following the TGA Report: “*Consultation: Therapeutic Goods Advertising Code - Proposed improvements including proposed framework for Schedule 3 medicine advertising*” (August 2017), the Therapeutic Goods Administration (TGA) released the updated draft *Therapeutic Goods Advertising Code 2018 (Draft New Code)* for consultation on 29 March 2018 and the consultation period closed on 27 April 2018.

The Code is a legislative instrument made under section 42BAA of the *Therapeutic Goods Act 1989 (Cth)* (the **Act**) by the Minister or their delegate. It is the key advertising compliance standard that sets out minimum requirements and underpins the regulatory framework for the advertising of therapeutic goods to the public.

The Act defines advertisement, in relation to therapeutic goods, as including; any statement, pictorial representation or design (however made) that is intended, whether directly or indirectly, to promote the use or supply of the goods.

This definition is very broad and captures therapeutic good advertisements that are published or broadcast in a number of media, including newspapers, magazines, television (including pay TV), radio, the Internet (including Facebook, Twitter and other social media) catalogues and point of sale material. It also captures the product label if it includes a statement, pictorial representation or design that is intended to promote the use or supply of a therapeutic good.

A useful comparison prepared by the TGA between the 2015 version (**Existing Code**) and the proposed 2018 version is available at: <https://www.tga.gov.au/sites/default/files/comparison-between-the-therapeutic-goods-advertising-code-2015-and-the-proposed-2018-code.pdf>

Some of the amendments are as follows:

- All guidance materials included in the Existing Code are now included in separate Code guidelines, including pre-approval guidance;
- Section 10 (**Effect**) of the Code has been amended to include some new requirements, including advertising for therapeutic goods must support the safe and proper use of therapeutic goods by presenting the goods in accordance with directions or instructions for use;
- Section 11(2)(d) (**What must advertisements contain – general rules**) of the Draft New Code is a new provision requiring Sponsors to alert the consumer of where they can obtain further important information about the medicine, including adverse reactions, precautions, contraindications and method of use;

- Section 20 (**Allergies**) is a new provision – stating that if therapeutic goods have a history of causing a serious allergic reaction in a particular patient group, advertising for those therapeutic goods must contain a warning applicable to that patient group, prominently displayed or communicated;
- Section 21 (**Consistency with public health campaigns**) is a new provision – If a relevant public health campaign is current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign and the other objects of the Code. Sponsors will therefore need to keep abreast of current public health campaigns, and compliance may have challenges if an advertising campaign is planned, booked and paid for well in advance;
- Section 23 (**Complementary medicines**): In relation to complementary medicines, the Draft New Code states that if an advertisement for a complementary medicine includes a claim based on evidence of a history of traditional use and paradigm, the reliance on this traditional use must be disclosed in the advertisement and the disclosure must be displayed or communicated in the advertisement. It may be unclear exactly what is a “traditional use” as compared to a non-traditional use; and
- Section 27 (**Sunscreens**) has a new provision relating to the advertising of sunscreens.

Once the TGA has considered feedback from this consultation and from the Therapeutic Goods Advertising Code Council (**TGACC**), final amendments will be made to the proposed draft Code and guidance document. At this stage it is anticipated that the new Code will come into effect from 1 July 2018.<sup>30</sup>



<sup>30</sup> <https://www.tga.gov.au/consultation/consultation-draft-therapeutic-goods-advertising-code-2018-and-associated-guidelines>

## Updates to the National Police Check Application Process

By Alison Choy Flannigan, Partner and Sarah Spear, Associate

### Aged Care

Since 2007, Commonwealth-funded Approved Providers have been required to undertake criminal background checks for all staff and volunteers to ensure that aged care is only undertaken by appropriate individuals.

Checks must be undertaken for individuals who are:

- staff members over the age of 16 and likely to have either supervised or unsupervised access to care recipients; or
- volunteers with unsupervised access to care recipients who are over the age of 16 (except where they are a full-time student, then over the age of 18).

The *Accountability Principles 2014* defines a “staff member” of an approved provider, as a person who:

- is at least 16 years old;
- is employed, hired, retained or contracted by the approved provider (whether directly or through an employment or recruitment agency) to provide care or other services under the control of the approved provider; and
- has, or is reasonably likely to have, access to care recipients.

Examples of persons who are staff members of an approved provider include:

- key personnel of the approved provider;
- employees and contractors of the approved provider who provide care to care recipients;
- allied health professionals contracted by the approved provider to provide care to care recipients;
- kitchen, laundry, garden and office personnel employed by the approved provider; and
- consultants, trainers and advisors for accreditation support or systems improvement who are under the control of the approved provider.

Examples of persons who are **not** staff members of an approved provider include:

- visiting medical practitioners, pharmacists and other allied health professionals who have been requested by, or on behalf of, a care recipient but are not contracted by the approved provider; and

- tradespeople who perform work otherwise than under the control of the approved provider (that is, as independent contractors).

Ideally the police check should be undertaken before commencing work, although there are allowances for exceptional circumstances.

The police checks only cover convictions in Australia. Staff and volunteers who have been a citizen or permanent resident of a country outside of Australia are required to sign a statutory declaration stating that they have not been convicted of a precluded offence.

The Act prohibits people being employed or volunteering in aged care if they have:

- a conviction for murder or sexual assault; or
- a conviction of (and sentence to imprisonment for) any other of assault.

Any other convictions should be assessed on a case by case basis.

Part 6 of the *Accountability Principles 2014* sets out the current requirements of police checks, which must be undertaken by an agency accredited by the Australian Criminal Intelligence Commission (**ACIC**) on a National basis.

The Approved Provider must ensure that the certificate is not more than 3 years old.

From 1 July this year, the process by which ACIC conducts checks has been significantly updated, and all accredited agencies will be required to enter in to new agreements with the ACIC which incorporate these new requirements. The timing of the rollout appears to vary.

Access to the National Police Checking Service is administered under the *Australian Crime Commission Act 2002 (Cth)* (**ACC Act**), and the ACIC is responsible for both allowing access to National Police Check information, as well as accrediting the providers of check.

From 1 July 2018 order for a Police Check to be undertaken, an ACIC agency will now have to sight four “identity documents”, which is replacing the current 100 points system for the confirmation of identity of police check applicants. The new categorisation of acceptable identity document will be consistent with:

- one “commencement of identity” document which must not be expired (such as a full Australian Birth Certificate, a current Australian Passport (not expired) or Australian Visa current at the time of entry to Australia as a resident or tourist, an ImmiCard issued by the Department of Home Affairs or other certificate of identity issued by the Department of Foreign Affairs and Trade (**DFAT**) (for refugees and non-Australian citizens for entry into Australia) or document of identity issued by DFAT (for Australian citizens or nationals of Commonwealth countries) or certificate of evidence of resident status;





- one “primary use in the community” document (such as a current Australian Drivers licence, Australian marriage certificate, current passport issued by a foreign government containing a valid entry stamp or visa for Australia), current proof of age or photo identity card issued by an Australian Government agency in the name of the applicant with a signature and photo, current shooters or firearms licence or for persons under the age of 18 with no other Primary Use in Community Documents a current student identification card with signature or photo; and
- two “secondary use in the community” documents (including but not limited to a certificate of identity issued by DFAT or document of identity issued by DFAT, convention travel documents (United Nations) issued by DFAT, other documents issued by foreign governments (for example drivers licence), Medicare Card, enrolment with the Australian Electoral Commission, security guard or crowd control licence, Centrelink or Veterans’ Affairs card, photo identity card issued by the Commonwealth or State Governments, bank card or credit card).

For some approved providers, identity documents are also now able to be sighted in additional ways: locally (face to face in person) and remotely (certified and uploaded or emailed).

The staff members ‘application pack’ (including application form, consent and identifying documents) will need to be destroyed after a minimum of 12 months and before a maximum of 15 months.

Health Care providers will need to ensure that agencies providing police checks for staff are appropriately accredited with ACIC, and that internal record keeping procedures are updated in line with the new information disposal guidelines.

For a full list of police check protocols, refer to the ACIC website: <https://www.acic.gov.au/our-services/national-police-checks>.

## Working with Children Checks

For hospital operators, working with children checks are different.

A single screening unit has been set-up in each state and territory to conduct working with children checks and issue the resulting cards, registrations or permits. The following state and territory screening units are the only organisations allowed, under legislation, to conduct working with children checks:<sup>31</sup>

- Australian Capital Territory - Access Canberra - Working with Vulnerable People
- New South Wales - Office of the Children’s Guardian
- Northern Territory - Northern Territory Government
- Queensland - Queensland Government Department of Justice and Attorney-General - Blue Card Services
- South Australia - Department for Communities and Social Inclusion
- Tasmania - Department of Justice
- Victoria - Justice and Regulation
- Western Australia - Department of Communities

At this time, the identity requirements for obtaining Working With Children Checks for employees and volunteers remain unchanged.

<sup>31</sup> <https://www.acic.gov.au/our-services/national-police-checking-service/find-out-more-information/working-children-checks#accordion-2>



## EU General Data Protection Regulation (GDPR) (Regulation 2016/679) – How is this relevant to the Australian Health and Lifesciences Sector?

By Alison Choy Flannigan, Partner and Nameeta Chandra, Associate

### Background

On 25 May 2018, the EU General Data Protection Regulation (GDPR) (Regulation 2016/679), came into effect, replacing the existing 1995 data protection directive.

The GDPR applies to all EU member states and to organisations in countries outside the EU that process data of individuals in the EU. The extended jurisdiction of the GDPR is arguably the most momentous change introduced by the Regulation and is of fundamental importance to the Australian organisations that are now covered by the GDPR.

Australian organisations must consider two important questions:

- (i) whether they are covered by the GDPR, and if so,
- (ii) whether their current privacy policies and practices reflect their legal obligations under the GDPR.

The Office of Australian Information Commissioner (OAIC), has published a useful resource to assist Australian organisations to undertake their obligations under both the GDPR and the *Privacy Act 1988* (Cth) (the **Privacy Act**) (<https://www.oaic.gov.au/agencies-and-organisations/business-resources/privacy-business-resource-21-australian-businesses-and-the-eu-general-data-protection-regulation>).

### What Australian organisations are covered?

The GDPR concerns the processing of personal data of individuals in the EU by a “controller” or “processor” with an establishment in the EU, or if not established in the EU, where:<sup>32</sup>

- (a) the processing activities are related to the offering of goods and services to individuals in the EU (irrespective of whether payment is required); or
- (b) if they monitor the behaviour of individuals in the EU (Article 3).

<sup>32</sup> Essentially, a “controller” refers to the natural or legal person, public authority, agency, or other body, alone or jointly with others, that determines the purposes and means of processing personal data, and the “processor” means the natural or legal person, public authority, agency, or other body that processes the personal data on behalf of the controller. (Article 4) The example given is that of a bank (the controller) that collects personal data from a customer for purpose of opening a bank account, and then provides it to another organisation to store (the processor).

Importantly, where the Privacy Act applies to the Commonwealth government, private sector organisations with an annual turnover of more than \$3 million and all private health service providers, the GDPR has extended application as it applies to Australian organisations of any size where their activities are captured in Article 3.

The OAIC has provided examples of when an organisation may be covered by the GDPR, including where:

- an Australian business has an office in the EU;
- an Australian business’ website targets EU customers (such as by allowing them to purchase goods and services in a European language and / or to affect payment in euros);
- an Australian business website mentions customers or users in the EU; and
- an Australian business tracking and profiling individuals in the EU.

Other examples of Australian organisations covered include universities which have campuses in the EU or maintain contact with alumni residing in the EU.

For the Australian health and lifescience sector, the GDPR may apply to:

- the monitoring of behaviour of individuals in the EU, for example, if an Australian company is the sponsor or the lead international site/co-ordinator of a clinical trial in a European country;
- pharmaceutical or medical device companies who have an office in a European country; or
- the offer for sale of therapeutic goods (including medicines, medical devices and complementary medicines) directly or indirectly through the internet targeting people who reside in a European country.

### Key concepts and obligations

The GDPR uses the concepts of “personal data” and “processing” (Article 4), which are defined as follows:

- personal data means any information relating to an identified or identifiable natural person; and
- processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as the collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination (or otherwise making available), alignment or combination, restriction, erasure or destruction of personal data.

Some of these concepts are reflected in the Privacy Act in relation to the collection, storage, use, disclosure, security and disposal of personal and sensitive information.

The requirement of “consent” is present in many of the responsibilities in the GDPR. Article 4 of the GDPR defines consent as “...freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her”.

The data controller needs to be able to demonstrate that the individual has consented to the processing. Consent is not freely given if the individual has no genuine or free choice or is unable to refuse or withdraw consent at any time (Article 7 and recital 42). Businesses also need to make the withdrawal of consent as easy as giving consent, and before individuals give consent, must inform individuals about this right to withdraw consent (Article 7(3)). When consent is given in the context of a written declaration, which also concerns other matters, it is to be clearly distinguishable from other matters and provided in an intelligible and easily accessible form using clear and plain language (Article 7(2)). Specific requirements apply to children’s consent.

The OAIC recommends that Australian organisations covered by the GDPR standardise their consent mechanism, so it reflects their obligations under both the GDPR and the Privacy Act.

The GDPR also introduces the following new and expanded rights for individuals:

- the erasure of data (or the right to be forgotten): Article 17
- the right to data portability – transporting data between controllers without hinderance: Article 20; and
- the right to object to the processing of data: Article 21

There are no equivalents to these rights in the Privacy Act, although Australian Privacy Principles (**APP**) may contain these rights in some form, for example APP 11.2, provides that APP entities must take reasonable steps to destroy or de-identify personal information that is no longer needed for a permitted purpose.

Other important obligations under the GDPR include mandatory data breach notification without undue delay and, where feasible, not later than 72 hours where a data breach is likely to “result in a risk for the rights and freedoms of individuals” (Article 33).

The GDPR requires data controllers to give individuals a range of prescribed information about the processing of their personal data (Articles 13 and 14).

## Penalties

The GDPR imposes substantial fines for organisations that fail to comply with the Regulation. In relation to breaches of certain articles a maximum fine of 20 million EUR, or up to 4 percent of the total worldwide annual turnover of the organisation (whichever is higher) may be imposed (Article 83).

## Approach

The recommendation for organisations is to avoid an alarmist approach to the Regulation as many organisations have already been required to comply with various privacy laws, whether in the EU under the existing 1995 data protection directive, or in Australia under the Privacy Act (or any of the state-based privacy laws). It is now just a matter of carefully reviewing those policies and practices to identify any “gaps”, and to amend as required. ■



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# MEET THE TEAM



## Alison Choy Flannigan

+61 2 9390 8338 • [alison.choyflannigan@holmanwebb.com.au](mailto:alison.choyflannigan@holmanwebb.com.au)

For every year since 2008, Alison has been selected by her peers for inclusion on the Best Lawyers list for Australia in the practice area of Health and Aged Care. Having been part of the health care and aged care sector Alison has an in-depth understanding of the health and aged care sectors and brings specialist legal expertise as well as commercial acumen and solutions. She also appreciates that issues for health and aged care providers often require urgent attention and makes herself available to her clients whenever she is needed. She has a passion and dedication to the sector which goes way beyond just being a lawyer in private practice – she strives to become the long term trusted advisor of her clients.

## 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](mailto:alison.choyflannigan@holmanwebb.com.au)

**Rachael Sutton**  
Partner – Workplace relations  
T: +61 2 9390 8422  
[rachael.sutton@holmanwebb.com.au](mailto:rachael.sutton@holmanwebb.com.au)

**John Van de Poll**  
Partner – Medical malpractice and discipline  
T: +61 2 9390 8406  
[jvp@holmanwebb.com.au](mailto:jvp@holmanwebb.com.au)

**Robin Young**  
Partner – Workplace relations  
T: +61 2 9390 8419  
[robin.young@holmanwebb.com.au](mailto:robin.young@holmanwebb.com.au)

**Zara Officer**  
Special Counsel – Medical malpractice and discipline  
T: +61 2 9390 8427  
[zara.officer@holmanwebb.com.au](mailto:zara.officer@holmanwebb.com.au)

### Melbourne

**Colin Hall**  
Partner – Medical malpractice and discipline  
T: +61 3 9691 1222  
[colin.hall@holmanwebb.com.au](mailto:colin.hall@holmanwebb.com.au)

### Brisbane

**Mark Victorsen**  
Partner - Medical malpractice and discipline  
T: +61 7 3235 0102  
[mark.victorsen@holmanwebb.com.au](mailto:mark.victorsen@holmanwebb.com.au)

**Heath Gleig-Scott**  
Partner – Property and Commercial  
T: +61 7 3235 013  
[heath.gleig-scott@holmanwebb.com.au](mailto:heath.gleig-scott@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](mailto:alison.choyflannigan@holmanwebb.com.au)

Editor: Alison Choy Flannigan

For all other enquiries please contact Adriana Giometti +61 2 9390 8456 or [Adriana.giometti@holmanwebb.com.au](mailto:Adriana.giometti@holmanwebb.com.au)

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**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 17  
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

#### ADELAIDE

Level 6  
55 Gawler Place  
Adelaide SA 5000  
Phone +61 8 7078 3100  
Fax +61 8 8219 9949

[www.holmanwebb.com.au](http://www.holmanwebb.com.au)

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