

## Markebeat M

Australia's Legal Environment – Health Law Update



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Welcome to the fourteenth issue of the Health Update – Sparkebeat, where Sparke Helmore's market leading national Health team brings you the latest in local news and knowledge from across Australia and abroad.

From Al scribes to surrogacy reform, this edition dives deep into the legal pulse of Australia's healthcare landscape. We explore the ethical and legal frontiers of artificial intelligence in clinical consultations, dissect the fallout from donor missteps at Monash IVF, and unpack the evolving standards for revisiting historical abuse settlements. Ground-breaking surrogacy reforms in WA, a new compensation pathway under the new Aged Care Act 2024, and the High Court's fresh take on reasonableness all signal a sector in flux. Add to that a spotlight on cybersecurity, a tragic inquest, and professional boundary breaches, this issue delivers a comprehensive snapshot of the challenges and changes shaping healthcare law today.

We hope you find this issue informative and useful. If there are any topics you would like us to cover in the future, please contact a member of our national Health team.

#### Sparke Helmore's national Health team

Our health team advises medical defence organisations, insureds (including hospitals, clinics, practitioners and other medical and allied health service providers), insurers, underwriting agencies cover holders and brokers, both locally and internationally including in the Lloyd's market.

Our team specialises in clinical negligence litigation, investigations, professional conduct hearings, and coronial inquiries. We also advise on matters related to regulatory compliance, policy drafting, coverage and indemnity issues.

This unique experience allows us to meet the needs of our clients regardless of jurisdiction, volume or complexity.

#### WHEN AI JOINS THE CONSULTATION - THE LEGAL IMPLICATIONS OF AI SCRIBES IN HEALTHCARE

Authors: Jason Kwan (Partner), Lani Carter (Special Counsel) and Ella Sourdin Brown (Law Graduate)

Cast your mind back to your latest medical appointment. Was your healthcare provider fully engaged in conversation with you instead of furiously typing away, trying to record your symptoms? If so, they may have had an 'Al scribe' doing the hard work for them.

Artificial intelligence (AI) transcription tools, or 'Al scribes', are transforming the role played by transcription in clinical care. Not only can Al scribes perform simple record dictation, but they can also intelligently summarise and analyse conversations. These tools have the potential to ease administrative burden, reduce staff burnout and improve bedside manner by allowing clinicians to focus on patient care.1

However, the use of AI scribes presents risks, especially when introduced without robust Al governance procedures. This article examines some of the key legal issues arising from the use of AI transcription tools in healthcare, including the application of privacy and surveillance laws and interaction with professional obligations that apply to medical practitioners.

#### Rise of the machines

Al is increasingly being used in healthcare for diagnostic purposes, particularly in radiology, dermatology, pathology and ophthalmology. One of the fastest growing and more mature use cases is the use of Al scribes. Al scribes generally operate in one of two ways:



Online Video Conferencing: audio is recorded using software and then downloaded2, or



Face-to face: a microphone is used to capture speech, which is then converted into text.3

These tools differ from conventional transcription devices because they utilise machine learning, which allows them to adapt without explicit instructions. They also incorporate natural language processing, enabling them to understand dialects, accents, and colloquialisms, and automatic speech recognition to convert audio into written text.

- Royal Australian College of General Practitioners, Artificial Intelligence (AI) Scribes (Fact Sheet, 21 July 2025).
  Gabrielle Samuel and Doug Wassenaar, 'Joint Editorial: Informed Consent and AI Transcription of Qualitative Data' (2024) 20(1-2) Journal of Empirical Research on Human Research Ethics
- A Baki Kocaballi et al. 'Envisioning an artificial intelligence documentation assistant for future primary care consultations: A co-design study with general practitioners' Journal of the American Medical Informatics Association 27 (11) (2020) 1695–1704.

#### **Privacy considerations**

The collection and handling of personal information by private health providers is governed by the *Privacy* Act 1993 (Cth) (**Privacy Act**), with the collection of sensitive information (which includes health information) subject to higher standards of protection.

Under the Privacy Act, an entity may only collect sensitive information if its collection is reasonably necessary for one or more of the entity's functions (in this case to provide medical services) and if the individual has provided their consent. Therefore, consent will need to be obtained from a patient before collecting personal information from them using an Al scribe. Ideally the consent should be expressly obtained from the patient in writing. Consent should also be informed, which may mean explaining to the patient how their personal information will be used by the AI model.

The Australian Health Practitioner Regulation Agency (AHPRA) recommends that practitioners inform patients about their use of AI transcription tools, provide information about how the AI transcription tool works and how it may impact the patient in terms of collection and use of their personal information.4

Unless consent is obtained, personal information that has been collected by an AI scribe must only be used and disclosed for the purpose for which it was collected, or a secondary purpose directly related to the primary purpose. For example, health information collected during a consultation should not be used for an unrelated secondary purpose such as improving the functionality of the AI scribe without the consent of the patient.

Healthcare providers using AI scribes should also check whether personal information is transferred outside of Australia. If so, adequate contractual protections need to be in place with the overseas recipient or the overseas recipient must be governed by substantially similar privacy laws.

The Privacy Act also requires an entity to take reasonable steps to protect personal information from unauthorised access. This could involve an entity conducting adequate due diligence to ensure the

safety of the AI scribe, including assessment of security measures to protect against cyber threats.

#### Surveillance in scrubs

In most states and territories, it is an offence to make an audio recording of a conversation or to communicate that audio recording to a third party without the consent of both parties.<sup>5</sup> These provisions apply to the use of AI scribes, which make an audio recording as part of the transcription process.

In order to ensure compliance with surveillance laws it is best practice for medical practitioners to obtain informed and express consent from patients before using an AI scribe to record any patient interaction (even in states where implied consent is sufficient).6 Obtaining informed consent involves ensuring an individual is aware their conversation is being recorded and that they understand the consequences of that recording, including how the information obtained will be used and when it will be disclosed.

#### Therapeutic Goods Act 1989 (Cth) classification

Currently, Al scribes are not regulated by the Therapeutic Goods Act (TGA) as they do not fall within the definition of a 'medical device'. This is because they are not supplied for the purpose of diagnosis, prevention, monitoring, or treatment, but rather to summarise clinical practice notes. This categorisation may change in the future as transcription devices become capable of proposing diagnosis or treatment options for patients based on symptoms disclosed during a consultation. Consultation is also being undertaken to consider whether the TGA is appropriate to meet the challenges associated with the increasing use of medical software and AI across the healthcare sector. Regulation by the TGA would mean AI scribes would need to be registered on the Australian Register of Therapeutic Goods and comply with certain safety, performance, and quality standards. A designated risk rating depending on the invasiveness of the tool will also need to be complied with.7

<sup>4.</sup> Australian Health Practitioner Regulation Agency, Meeting Your Professional Obligations When Using Artificial Intelligence in Healthcare (Web Page, 2025) https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.

Sections 4, 5, 7 Listening Devices Act 1992 (ACT); Sections 7,11,12 Surveillance Devices Act 2007 (NSW); Sections 11 and 15 Surveillance Devices Act 2007 (NT); Sections 43 and 45 Invasion of Privacy Act 1971 (QLD); Sections 4 and 12(1)(a) Surveillance Devices Act 2016 (SA); Section 5, 11, 12 Listening Devices Act 1991 (TAS); Sections 6 and 11 Surveillance Devices Act 1999 (VIC); Sections 5, 9, 34 Surveillance Devices Act 1998 (WA).

<sup>6.</sup> Medical Indemnity Protection Society, 'Al Scribes: Medicolegal Issues' (Web Page, 2024) <a href="https://support.mips.com.au/home/ai-scribes-medicolegal-issues">https://support.mips.com.au/home/ai-scribes-medicolegal-issues</a>

Section 41BD Therapeutic Goods Act 1989 (Cth); Department of Health and Aged Care, 'Artificial Intelligence (AI) and Medical Device Software' (Web Page, 2024) <a href="https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/manufacture-specific-types-medical-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/artificial-devices/ar intelligence-ai-and-medical-device-software>.

#### Interaction with professional obligations

Regardless of whether AI scribes are regulated by the TGA, health care practitioners need to remain responsible for delivering safe and quality care and for ensuring their own practice meets the professional obligations set out in their codes of conduct. Practitioners must remain responsible for the accuracy of the transcript and apply critical human judgment to any output of AI. Practitioners should also have a sufficient understanding of the AI scribe so that they can use it safely and in a way that meets their professional obligations.

Professional obligations also require that medical practitioners ensure the confidentiality and privacy of their patients as required by privacy and health record legislation. This includes ensuring that data is collected, stored, used and disclosed in accordance with legal requirements including those relating to privacy.

#### Impact on ways of working

While AI transcription tools may save medical practitioners time in note taking, the potential impact on practitioner performance is less certain. For example, there may be a greater accuracy and clarity that comes from a practitioner manually summarising and distilling the key findings from a consultation that may be lost when relying on Al transcription. It may be that practitioners also need to be taught the optimal way in which to use Al scribes, including how to use prompts effectively and how to analyse the outputs to identify any gaps in information. It is also crucial for medical practitioners to retain their independent judgement in patient care. Al scribes and other emerging technology should not replace the clinician's expertise and ability to assess the broader context and discern nuances that AI tools may overlook.



# RESTRICTIVE PRACTICES IN AGED CARE – NAVIGATING COMPLIANCE UNDER THE NEW LEGAL FRAMEWORK

Authors: Lani Carter (Special Counsel) and Anthony Tsecagias (Paralegal)

The Aged Care Quality and Safety Royal Commission (the Aged Care Royal Commission) heard stories about the overuse (and in some cases, abuse) of restrictive practices in aged care facilities across Australia. Similar concerns were raised in the Royal Commission into Violence, Abuse, Neglects and Exploitation of People with Disability. Recommendations were made in both Royal Commissions to limit the use of restrictive practices and to provide for oversight and additional safeguards.<sup>1</sup>

The Aged Care Royal Commission Final Report (**the Final Report**)<sup>2</sup> noted that restrictive practices:

...impact the liberty and dignity of people receiving aged care. The right to personal autonomy is recognised in domestic laws and international human rights instruments. International human rights conventions, to which Australia is a signatory, recognise rights such as self-determination, liberty and security of the person, and recognition and equality before the law. The common law in Australia recognises that each person has the right to choose what occurs with respect to their own body. Providing care or treatment, or detaining someone without their consent, can be a civil wrong or a criminal offence.

Where restrictive practices are used 'without clear justification and clinical indication' the Commissioners concluded 'we consider this to be abuse'.<sup>3</sup>

The new Aged Care Act 2024 (Cth) (the Act) and the Aged Care Rules 2025 (the Rules) are due to come into force 1 November 2025. The Act and the Rules implement the recommendations of the Aged Care Royal Commission and are intended to improve safeguards regarding the use of restrictive practices and strengthen regulatory requirements. Under the new Act, restrictive practices are to be used as a last resort and in a manner that upholds the new Aged Care Standards and Statement of Rights enshrined in the Act.

It is a condition of registration that a registered provider must comply with requirements prescribed by the Rules relating to the use of restrictive practices.<sup>4</sup>

#### What are restrictive practices?

A restrictive practice in relation to an individual is defined under 17 of the Act as:

'... any practice or intervention that has the effect of restricting the rights or freedom of movement of that individual.'

There are five types of restrictive practices, namely – chemical, environmental, mechanical, physical and seclusion.<sup>5</sup>

<sup>1.</sup> See Recommendation 17: regulation of restraints and Disability Royal Commission Report entitled: Reducing Restrictive Practices: A Review of Evidence-Based Alternatives

<sup>2.</sup> Care, Dignity and Respect (the Final Report) (Vol 3A)

<sup>3.</sup> Final Report, Volume 2, p 97.

<sup>4.</sup> Section 162 Aged Care Act 2024 (Cth).

<sup>5.</sup> See Division 2 – Restrictive Practices – Aged Care Rules 2025.



A **chemical restraint** uses a medication or a chemical substance for the primary purpose of influencing behaviour. A common chemical restraint is the use of psychotropics such as antidepressants or antipsychotics. Chemical restraints do not include medications prescribed for treatment for a physical or mental illness or condition or for end-of-life care.



**Environmental restraints** are restrictions on access to areas and activities for the primary purpose of influencing behaviour. This might include pushing a bed up against a wall, the locking of doors or the use of gates or keypad entry and exit. This will not include areas restricted for safety such as kitchens or medication storage areas.



**Mechanical restrictions** involve the use of a device to prevent, restrict or subdue movement for the primary purpose of influencing an individual's behaviour. These may include bed rails, or lowering beds to make it difficult for an individual to get out, tray tables, princess chairs (also known as tilt-in-space comfort chairs) belts or straps, harnesses, gloves or other restrictive clothing – but will not include devices used for therapeutic or nonbehavioural purposes.



Physical restraints are a practice or intervention involving the use of physical force to restrict a recipient for the primary purpose of influencing their behaviour.



Finally, **seclusion** is considered a restrictive practice that involves the confinement of an individual in a room or space at any time of the day or night where voluntary exit is prevented or not facilitated, or it is implied that voluntary exit is not permitted for the primary purpose of influencing an individual's behaviour. Most facilities will have restrictions on exiting a facility after hours, but this will not be considered a restrictive practice where the primary purpose of that restriction is the safety of residents and not influencing their behaviour.

As we see from the definitions, the key issue in determining whether something amounts to a 'restrictive practice' is where the primary aim is to influence behaviour. This means that where the primary goal is directed at another outcome, the use of the measure may not be a restrictive practice as defined by the Act. The issue of whether a practice is being used for the primary purpose to influence behaviour or, say, for the primary purpose of safety is not straightforward and will be considered on a caseby-case basis.6

#### Why are restrictive practices used?

An aged care facility may need to make use of restrictive practices for a number of reasons – but the most common uses are:

- a. to calm a resident
- b. to keep a resident away from unsafe areas or other residents
- in an emergency, or
- where the resident is a risk to themselves or others.

#### **Risks**

All restrictive practices inhibit the exercise of an individual's liberty, and their use must be considered.

Where restrictive practices are used without protective measures, there is potential for claims to arise for physical and psychological injury along with claims for the deprivation of liberty including the common law tort of false imprisonment.

The use of restrictive practices may form a valid part of a care regime – but their use is not without risk. The use of restrictive practices may result in physical harm in terms of lacerations, bruises, pain and may lead to bedsores when overused. They also have the potential to negatively affect a person's mental health causing distress and confusion and potentially diagnosable psychological illness.

A number of Courts and Tribunals have considered whether certain measures amount to restrictive practices under the previous Aged Care Act 1997 (Cth) it is outside the scope of this article to canvass them all but see for example VZM [2020] NSWCATGD 25 and HZC [2019] NSWCATGD 8.



#### Regulatory and reporting requirements

Pursuant to s 18(1)(a)-(g) of the Act, restrictive practices may be used:

- as a last resort
- after considering the likely impact on the individual
- where alternatives have been exhausted to the extent this is possible
- alternative strategies have been used or considered and that use, or consideration is documented
- that they are used in proportion to the risk of harm to the individual or other persons
- where informed consent is given by the person or their Restrictive Practices Nominee<sup>7</sup>
- where provision is made for monitoring and review.

All registered providers must make use of the Serious Incident Response Scheme (**SIRS**) reporting mechanism to report serious incidents including where they arise as a result of the use of restrictive practices.

#### Immunity from suit

The Act provides for immunity from civil and criminal penalty arising from the use of restrictive practices where:



 informed consent was given to the use of the restrictive practice, and



b. the restrictive practice was used in accordance with the requirements prescribed by the *Aged Care Rules 2025*.

<sup>7.</sup> A Restrictive Practices Nominee is a person, chosen by the aged care recipient, who can provide informed consent for the use of restrictive practices if the recipient lacks decision-making capacity.

<sup>8.</sup> See 162-70 of the Aged Care Rules 2025.

#### Restrictive practices – a last resort

Any practice that inhibits the exercise of a person's liberty must be used as a last resort, used sparingly, and involve informed consent.

#### Providers should:



Ensure that a medical practitioner has assessed the individual and recommended the use of a restrictive practice in a behaviour support plan before implementation.



Ideally, that report must thoroughly consider the available alternatives to restrictive practices and weigh those alternatives (or indeed, recommend the exploration of alternatives before restrictive practices are implemented).



Organisations would be well-placed to familiarise themselves with the suite of alternatives to restrictive practices and keep up to date with research into the efficacy of those alternatives.



Obtain informed consent to the use of restrictive practices – either from the individual or from their 'restrictive practices substitute decision maker' if they do not have capacity.



Ensure that staff are aware of their obligations under the Rules to properly document, monitor and review the recommended frequency, duration and intended outcome of the implementation of a restrictive practice.



Ensure that behaviour support plans are reviewed on a regular basis and as soon as practicable after any change in the individual's circumstances.8



Ensure staff are familiar with the SIRS for serious incidents arising from the use of restrictive practices.

Underwriters would be well advised to ensure that facilities they insure have policies and procedures in place to ensure compliance with these more onerous restrictive practice obligations arising under the new Act.

## EMBRYOS, ETHICS AND ACCOUNTABILITY: THE MONASH IVF SCANDAL UNPACKED

Authors: Kerri Thomas (Partner), Dinah Amrad (Associate) and Fenella Selvaratnam (Paralegal)

Monash IVF, a prominent fertility service provider, is currently facing intense legal and regulatory scrutiny following a series of high-profile incidents that have raised serious concerns across Australia's assisted reproductive technology (ART) sector. These include a landmark class action settlement over genetic testing and, more recently, two deeply troubling clinical errors: an embryo mix-up in Brisbane and an incorrect embryo transfer in Melbourne. Together, these cases raise complex questions around law, ethics, and policy.

What happened?

Two separate embryo mix-up incidents have raised significant legal, ethical, and regulatory concerns, for which Monash IVF has issued formal apologies, as outlined below.

Firstly, in early 2023, a Brisbane woman was mistakenly implanted with another couple's embryo. She carried the pregnancy to term and gave birth to a child who is not genetically related to her or her partner. The error only came to light in February 2025, when an additional embryo was later discovered in storage, triggering what many regard as one of Australia's most serious ART mistakes.

Separately, on 5 June 2025 at Monash IVF'S Clayton clinic, a patient was implanted with her own embryo instead of her partner's embryo, contrary to the couple's agreed treatment plan. This error was attributed to manual input failure, despite partial digital safeguards being in place. While this case did not involve disputed parentage, it represented a significant breach of informed consent and autonomy.

While Monash IVF has apologised for both embryo mix-up incidents, these events have raised significant concerns. Victoria's Health Minister, Mary-Anne Thomas, confirmed that the State health regulator is investigating the Melbourne case, with Monash IVF

required to cooperate fully and provide transparent explanations. However, the outcomes of these investigations remain confidential.

In addition to the embryo mix-ups, Monash IVF faced a class action from over 700 former patients regarding its genetic testing practices between May 2019 and October 2020. These plaintiffs alleged that Monash IVF failed to disclose the risk of false positives in non-invasive pre-implantation genetic testing, leading to viable embryos being discarded, and raised further concerns about unauthorised research, forged consent forms, and document destruction. Monash IVF recently agreed to a \$56 million settlement, providing many patients with a sense of closure after years of legal and emotional challenges.



#### Legal and policy implications

The embryo mix-up incidents highlight the significant liability risks faced by healthcare practitioners and their insurers. In Brisbane, the parentage dispute demonstrates how complex ART claims can place clinicians at the intersection of family law and medical negligence, with the potential for substantial damages. In Victoria, the breach of consent underscores the critical need to follow patient treatment plans precisely, as even minor deviations can result in negligence claims, loss of patient choice, and psychological harm.

Collectively, these cases expose gaps in Australia's fragmented IVF regulatory framework and emphasise the importance of robust risk management systems. Without a national regulator, oversight remains inconsistent. These incidents have prompted calls for unified national standards, mandatory registration for embryologists, and stronger safeguards to restore public trust.

#### **Takeaway points**

High-profile incidents at Monash IVF have brought greater public awareness to the risks associated with assisted reproductive technology, with reputational damage serving as a strong deterrent for other providers. These IVF errors are likely not isolated; rather, they reveal deeper systemic vulnerabilities with far-reaching implications.

For healthcare providers, these cases highlight the need for rigorous clinical discipline, strict adherence to consent protocols, and robust risk management. For regulators, they underscore the urgent need for a cohesive national oversight framework that prioritises safety, transparency, and accountability.

A broader concern is the increasing commercialisation of assisted reproduction, where rapid industry growth and financial incentives may sometimes conflict with patient safety and ethical standards.

Above all, these cases serve as a reminder that patients and families must remain at the centre of every decision. When trust is compromised, the legal system plays a vital role in ensuring accountability, supporting those affected, and driving improvements in clinical practice.

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# IN CONVERSATION WITH ALISON ROENNFELDT: BREATHING NEW LIFE INTO REPRODUCTIVE SCIENCE



Alison is a final-year PhD candidate at the University of Adelaide in the School of Biological Sciences and Robinson Research Institute. Alison is also President of the Adelaide Protein Group and member of the Australian Society for Biochemistry and Molecular Biology.

Recently, Sparke Helmore's Lani Carter sat down with Alison to discuss her research.

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Good afternoon, Alison. Thank you for joining us at *Sparkebeat* – Sparke Helmore's Health Law publication.

Can you start by telling us a little about yourself and your research?

I commenced a Bachelor of Science (Advanced) degree in 2018, finishing with majors in Biochemistry and Genetics. When I began my degree, my initial plan was to ultimately become a high school science and biology teacher. However, I became drawn to the complexities of molecular biology and learning how the body works, how diseases develop and how we can treat diseases. After completing my Honours degree in Molecular and Biomedical Science, I absolutely fell in love with research and how the understanding of basic science can translate to treating disease and improving human health. Thus, in 2022, I commenced a PhD in biochemistry at The University of Adelaide, supervised by Associate Professor Dan Peet, Dr David Bersten and Professor Darryl Russell, which I am on track to finish in early

My research is focussed broadly on understanding the role of low oxygen (hypoxia) in both normal physiology and disease and the development of systems that allow us to measure oxygen sensing pathways in cells. In particular, I have investigated the role of low oxygen in both female reproduction (particularly ovulation) and in numerous disease contexts including metabolic disease and cancer. Ultimately, I am interested in understanding how cells work and how they can translate external signals (i.e. a decrease in oxygen) into a physiological response.

Aside from research, I am a passionate science communicator and teacher. I have been fortunate to teach numerous undergraduate laboratory classes and have been involved in many forms of outreach, including Open Days and Orientation weeks. I have also travelled to Ocean University, China, which is a partner university to the University of Adelaide, to teach second and third year cell biology and biotechnology courses as part of their Haide College program. I highly value science communication and actively present my research at numerous conferences each year, while also being the President of the Adelaide Protein Group, which holds numerous events each year for molecular and biomedical scientists in Adelaide to share their research and build their network.

This year, I was co-author on a Nature Communications article, which shared the development of our dFLASH fluorescent reporter system to assess changes in signalling pathways in cells. I have also recently submitted my findings investigating the role of hypoxia in ovulation for publication, which is currently under review.

Can you start by explaining, in simple terms, what hypoxia signalling is and why it matters in physiology?

The hypoxic response pathway (or hypoxic signalling) is induced in cells of the body when the oxygen demand of the cell exceeds supply. Oxygen is required within cells to produce high levels of energy and for numerous biological reactions. When oxygen levels decrease, the cell must switch to an adaptive 'survival' mode in order to withstand these new conditions. One of the key pathways which is activated by a decrease in oxygen is the Hypoxia Inducible Factor (HIF)

pathway, where the HIF proteins increase their levels and become active. These HIF proteins are essential for a cell to respond to the decrease in oxygen and they initiate the required signals for cell survival. Our lab is interested in investigating how these HIF proteins work, how they are regulated, and how we can manipulate their activity to treat disease.

The hypoxic response pathway plays a very important role in both normal physiology and disease. Interestingly, a decrease in oxygen during embryo development is what promotes the formation of blood vessels and it is the HIF proteins that control this. Likewise, activation of the HIF proteins is very important in the production of red blood cells, and drugs that activate the HIF pathway are used to treat some forms of anemia. In female reproduction, eggs (oocytes) are housed within structures called follicles prior to their release. Just prior to ovulation, these follicles undergo a decrease in oxygen, and during my PhD I have investigated the functional importance of this decrease in oxygen during ovulation. On the flip side however in a disease context, solid tumours often contain a hypoxic core, which drives a HIF response that promotes cancer cell growth and survival. Thus, both activation and inhibition of the HIF pathway is of great interest therapeutically, highlighting the important role of hypoxic signalling throughout the human body.

Your research focusses on hypoxia's role in ovulation. What drew you to investigate this link, and what have you discovered?

After completing my honours, I was wanting to expand my skill set and learn a new field of research. I have always been interested in women's health and the treatment of reproductive-related diseases, in particular given I have multiple friends who have endometriosis and other similar diseases. Hypoxic signalling had always been assumed to contribute to ovulation, however the exact mechanism of how this contributes to ovulation and the importance of this remained undefined. Given my experience in working with the hypoxic response pathway and HIF proteins in my Honours, I was interested in exploring this in the context of ovulation.

In my research, we have found that two different related versions of the HIF proteins, HIF-1 and HIF-2, are differentially regulated and activated during ovulation. I primarily focussed on HIF-2 and showed that it is turned on in response to the key ovulation inducing hormone (human chorionic gonadotropin). Interestingly, our studies in mice showed that

inhibiting HIF-2 did not lead to decrease in ovulation, but instead changed the cells to display more proovulation behaviour. Through this research we were able to show how the HIF-1 and HIF-2 proteins have different roles in ovulation and the important role of decreasing oxygen in promoting these signalling pathways.

Are there potential clinical applications for your findings - for example in infertility treatment or women's reproductive health more broadly?

When we treated mice with a HIF-2 inhibitor, we surprisingly saw changes in cell responses which were similar to that of changes which promote ovulation. We therefore hypothesise that inhibitors of HIF-2 could be used to activate ovulation in a disease context. This could have future applications in IVF or other infertility treatments where ovulation is to be induced, and may therefore have therapeutic applications in helping women with reproductive diseases such as endometriosis or poly cystic ovarian syndrome (PCOS) to get pregnant. These results are preliminary however, and do require significant further research prior to their translation in a therapeutic setting. However, gaining this understanding of how the HIF proteins contribute to ovulation together contributes to the greater understanding of how to manage and treat female reproductive disorders.

Does hypoxia play a role in other physiological symptoms beyond reproduction - and could understanding these pathways change how we approach certain diseases?

Although it might seem counterintuitive, numerous organs within the body are under varying levels of hypoxia and these changes in oxygen levels between tissues is essential in maintaining tissue response and function. One particularly therapeuticly-relevant aspect of hypoxia biology is that over 90% of solid tumour cancers (i.e. most cancers that are not blood cancers) display a decrease in oxygen, activating this HIF pathway response. As the HIF pathway acts to promote cell survival under low oxygen conditions, in the context of cancer, the HIF proteins actually act as key drivers of cancer and can promote tumour cell growth. As a result, research into finding drugs which inhibit the HIF proteins has been of high priority in recent times. A very good HIF-2 specific inhibitor has been developed and is used to treat clear cell renal

cell carcinoma in some countries. The development of a potent and selective HIF-1 inhibitor however remains unresolved, largely due to the instability of this protein both in and outside of cells. The quest to find a specific and potent HIF-1 inhibitor remains a large focus for many research groups in the hypoxia field, and the identification of such an inhibitor would provide a break through in the treatment of solid cancers.

Our lab has been contributing to this work through the development of our 'dFLASH' reporter system. This system consists of signal-controlled fluorescent proteins which can be used in cells to assess the activity of HIF-1. We are actively applying the HIF-dFLASH system to complete drug screening for novel HIF-1 inhibitors and other small molecule regulators of the HIF pathway and aim for this to ultimately contribute to the therapeutic targeting of the HIF pathway to treat cancer and other associated diseases in the future.

What are some of the biggest challenges in studying hypoxia in living systems, and how do you overcome them in your lab work?

As you can imagine, growing cells in a hypoxic environment is not straight forward and can be technically challenging! To do this in the lab, we have a 'hypoxia chamber'. This is essentially a sealed chamber which is temperature, humidity and gas controlled. We use nitrogen gas to reduce the oxygen levels as desired (generally to 0.5% oxygen) and can grow our cells in there when wanting to understand their responses to hypoxia. As an alternative and simpler method to activate the HIF pathway we can also treat the cells with drugs, which inhibit oxygensensing enzymes in cells, allowing us to mimic a hypoxic response. Most commonly, we use this drug treatment method as it is a lot easier and allows us to manipulate our cells throughout our experiments. However, in all cases we need to confirm our experiments under hypoxia using the hypoxia chamber to confirm the response is physiologically relevant.

Another challenge is that different cell types can respond differently to hypoxia. For example, some cells only express HIF-1 and not HIF-2, or others may induce less of a response compared to others. This is generally representative of what happens throughout the human body, however this highlights the importance of not generalising the cellular response of one cell type to all other cells. Although we have standard cell lines we use widely for assessing responses to hypoxia in the lab, we always aim to confirm our conclusions

across multiple cell types which are representative of the dieases/context of interest and if relevand an animal model of the disease. This is essential to move forward with any research related to human health and disease and allows findings to be translated into human treatments.

What are the next steps in your research and what kinds of collaborations – academic, clinical or industry – would help you translate your findings into practical healthcare outcomes?

I am currently in a transition phase where I am looking to finish up my PhD research, and move onto working as a post-doctoral researcher in mid-2026. Thus, one of my current priorities is teaching the next generation of PhD students in our lab to continue my projects and move them towards therapeutic applications.

One of my projects in particular is in the process of putting together a team of multidisciplinary researchers to achieve our end goal. In this project, we used our dFLASH system to complete drug screening for inhibitors of an enzyme called FIH, which responds to oxygen and controls metabolism. We believe this drug could be used in the future to treat metabolic diseases such as obesity or type II diabetes, and are working towards improving the potency and specificity of the drug to move it towards therapeutic application. As I am forever learning however, the process of drug discovery is long and requires experts from many different areas of biology and chemistry.

We are currently looking to partner with both academic and industry groups to help drive and fund the drug development process, with key input from clinicians on the therapeutic areas we need to address with our drug and what the current competing drugs are. With the help of this multi-faceted team we are hoping to ultimately develop a drug which can be used to treat obesity and related diseases which has less side effects than current weight loss drugs (such as Ozempic) and maintains weight loss over time.

Similarily, although my research into the role of hypoxia in ovulation is a long way from therapeutic translation, its potential application to this would also require a team of academic, industry and clinician experts to talor the therapeutic targeting of the pathway for translation into a reproductive disease treatment.



# THE TEST TO SET ASIDE A PREVIOUS SETTLEMENT AGREEMENT - STATE OF NEW SOUTH WALES V LSR3

Authors: Emily McKeowen (Partner), Alexandra Kuczerawy (Special Counsel) and Lauren Walker (Lawyer)

The New South Court of Appeal recently handed down its decision in *State of New South Wales v LSR3* [2025] NSWCA 151.

The Court of Appeal upheld the finding of the primary judge that Part 1C of the *Civil Liability Act 2002* (NSW) (**CLA**) does not require that the question of whether to set aside a prior settlement agreement for a historical abuse claim be determined separately and prior to the hearing of the underlying claim.

#### NSW legislative framework

In response to the recommendations made by the Royal Commission into Institutional Responses to Child Sexual Abuse in 2017, all states and territories enacted legislation that enables courts to set aside previous settlement agreements in historical child abuse claims.

In NSW, Part 1C of the CLA came into effect on 18 November 2021 and enables courts to set aside previous settlements of child abuse claims that are deemed to be an 'affected agreement'.

Section 7C of the CLA defines an 'affected agreement' as an agreement that is:

- entered into before the removal of the limitation period in 2016 and the claim was subject to an expired limitation period, or
- entered into before the commencement of Part 1B of the CLA in 2016, which allowed a claim to be brought against an unincorporated organisation and involved an unincorporated organisation that would have been liable had Part 1B been in force, or
- entered into before the commencement of Part 1B and is not just and reasonable.

In determining whether it is 'just and reasonable' to set aside a previous settlement agreement, the courts can have regard to the amount paid to the survivor, the bargaining position of the parties (including if they were legally represented), the conduct of the defendants and their legal representatives, the defences raised by defendants and any other matter that the court considers relevant.

#### Background

In LSR3, the Plaintiff previously brought claims for compensation for child abuse against multiple defendants including the State of New South Wales (the **State**) and South Eastern Sydney Local Health District of Caringbah (**SESLHD**). Those claims were settled on terms that included the payment of money. Settlement agreements giving effect to the settlements were entered into in 2003 and 2017.

The Plaintiff subsequently sought to revisit these claims on the basis that it was 'just and reasonable' to do so under Part 1C of the CLA. In 2024, the Plaintiff filed a Statement of Claim in the Supreme Court of NSW seeking orders that included the setting aside of the prior settlement agreements.

The State and SESLHD applied to have the question of whether the previous settlement agreements should be set aside determined separately and prior to the hearing of the Plaintiff's underlying substantive claim.

At first instance, Faulkner J refused to grant the application for separate questions noting several material difficulties, including that:

- a. the scope of the controversy remained largely undefined in the lack of any defences having been filed by the State and SESLHD
- b. there was a potential for prejudice against the Plaintiff, particularly if his credit was the subject of

both the separate questions (for the Part 1C issue) and the final hearing, and

c. an order for separate questions would likely cause delay.

The State and SESLHD sought leave to appeal from the decision on the basis that the primary judge had misconstrued ss 7C and 7D of the CLA as permitting the Plaintiff to proceed with the cause of action prior to the setting aside of the previous settlement agreements, which had the effect of preventing the Plaintiff from maintaining the cause of action.

#### Decision of the NSW Court of Appeal

The NSW Court of Appeal dismissed the appeal finding that an order for a determination of separate questions is a matter of practice and procedure that involved the exercise of judicial discretion. Appellate courts are required to exercise caution and restraint when reviewing appeals from a decision of practice or procedure with the consequence that a 'heavy burden' lies on an applicant, in this case the State and SESLHD. In this instance, the Court held that no error of principle had been identified nor any convincing basis established warranting a grant of leave to appeal the primary's judge's decision.

Separately, the Court of Appeal noted Part 1C of the CLA does not mandate that an application to set aside an affected agreement be determined in advance of the hearing of an underlying claim. However, the Court acknowledged that there may be cases where a separate determination of questions is appropriate, citing EXV v Uniting Church in Australia Property Trust (NSW) [2024] NSWSC 490. In that matter the Church filed a Defence pleading the prior settlement deed as a complete bar to the plaintiff's claim. The Plaintiff subsequently filed a Notice of Motion seeking to set aside the settlement deed under Part 1C. Justice Weinstein had allowed the Plaintiff's application to determine the Part 1C issue as a preliminary point prior to the underlying claim (and in that matter declined to set aside the previous deed, the effect of which was that the Plaintiff was barred from proceeding with his claim against the Church).

The Court of Appeal also acknowledged with approval, the primary judge's assessment of competing considerations in determining whether to order a separate determination of questions. Consideration was given to the degree of overlap between the evidence that would be adduced at the hearing of the separate question and at the hearing of the underlying claim.

#### Implications for insurers and health organisations

The Court of Appeal's decision confirms that the exercise of the courts' discretion to set aside an 'affected agreement' will not necessarily be determined separately and prior to the hearing of the underlying claim. Practically this may mean defendants will need to incur the costs of preparing the matter fully to a final contested hearing, on both the Part 1C issue and the substantive claim.

A defendant wishing to obtain an order for a separate determination of questions should first file a defence. This is to ensure the proper identification of the issues in the proceedings and the potential degree of overlap between the evidence that would be adduced at the hearing of the separate question and at the hearing of the underlying claim.

In determining whether to grant an order for a separate determination of questions, the courts will continue to consider issues of delay resulting from the separate determination, any prejudice to the plaintiff in having to demonstrate the strength of their prospects before the final hearing and matters of credit. As Faulkner J held at first instance, in cases involving child abuse it is undesirable for plaintiffs to be required to give evidence and be cross-examined twice.

It is expected that plaintiff survivors will continue to come forward and reagitate their settled claims. If not already, it is recommended that health organisations and insurers undertake a review of their closed claims to identify settlement agreements that could be set aside as an 'affected agreement'.



#### UNDERSTANDING WA'S GROUND-BREAKING SURROGACY REFORMS

Authors: Aimee Dash (Partner) and Yumi Oh (Lawyer)

Western Australia's current assisted reproductive technology (**ART**) and surrogacy laws are more than 30 years old and have been described as 'no longer reflecting modern families or reproductive rights'. In response, WA has recently introduced the Assisted Reproductive Technology and Surrogacy Bill 2025, a major reform aimed at making IVF and surrogacy more accessible, inclusive and reflective of contemporary values. The Bill removes outdated requirements, such as the need to prove medical infertility before accessing IVF. This reform aims to bring WA closer in line with laws in other Australian jurisdictions.

#### The heart of the reforms: equality of access

Currently, all surrogacy arrangements in WA are governed by the *Surrogacy Act 2008* (WA) (**Surrogacy Act**). These arrangements require a written agreement approved by the Western Australian Reproductive Technology Council, along with independent counselling, medical and psychological assessments, and legal advice for all parties involved.

Under the current law, only heterosexual married or de facto couples, and single women who are unable to conceive or carry a pregnancy, are eligible to enter into altruistic surrogacy agreements. This framework excludes individuals based on sex, relationship status, gender identity, intersex status and sexual orientation.

The proposed legislation seeks to address these inequities by expanding access to fertility treatment regardless of a person's sex, gender identity, sex characteristics, relationship status or sexual orientation. For instance, the Bill uses gender inclusive language, allows single men and same-sex couples to access ART services including surrogacy, and enables women in same-sex relationships to undergo

reciprocal IVF – where one partner's egg is used for the other to carry the pregnancy, enabling both to share a biological and gestational connection to the child.

These changes are intended to bring WA into alignments with both the *Sex Discrimination Act 1984* (Cth) and the *Equal Opportunity Act 1984* (WA). It has been noted that the current legal focus on women fails to acknowledge ART procedures that treat male infertility, and excludes non-binary, intersex and transgender individuals who are not women but can still access IVF and other uterine procedures. The shift toward gender inclusive language also helps to reduce the stigma that infertility is solely a women's issue.

#### Streamlining the system: process and oversight

The Reproductive Technology Council (**RTC**) of Western Australia has long played a key regulatory role under the Surrogacy Act, including approving surrogacy arrangements before the birth mother becomes pregnant. Under the new framework, the RTC will be disbanded and replaced by the WA ART Advisory and Review Board (the **ART Board**), which will assume a more limited and focused role. Fertility clinics have indicated that this will improve efficiency by removing administrative burdens that do not contribute meaningfully to safeguards for people using, or born through, ART.

The Bill removes the requirement for RTC approval in several areas, including extending embryo storage limits and granting general approval for the export of donor material. It also streamlines processes for approving genetic testing of embryos to avoid the conception of a child with a serious inheritable condition.

The ART Board will retain responsibility for approving ethically complex procedures that are permitted in other Australian jurisdictions but currently prohibited in WA. These include the use of a deceased person's sperm by a surviving partner, and genetic testing of embryos for tissue matching – enabling the selection of an embryo that could provide stem cell therapy to treat a close relative.

Currently, WA law permits a designated hospital officer to authorise the removal of gametes from a recently deceased person at the request of their spouse or de facto partner, provided there is consent (or no reason to believe that the person objected). However, while removal may be allowed, existing legislation prohibits the posthumous use of those gametes in assisted reproduction – even where the person had stored them prior to death with written consent for their use by a surviving partner.

Pre-implantation genetic testing (**PGT**) is currently permitted in WA to screen embryos for genetic diseases or disorders that would affect a child born. PGT can also be used together with human leukocyte antigen typing to identify embryos with tissue types compatible with an existing sibling or close relative who may benefit from stem cell therapy. However, under the current Human Reproductive Technology Act 1991 (WA), this use of PGT for tissue matching is only permitted if the parents are already eligible for IVF. The new legislation proposes to remove this restriction, allowing PGT for tissue typing more broadly.

#### Rights and identity: empowering donorconceived people

In the early years of ART, anonymity for both donors and recipients was widely encouraged by medical providers, largely due to the stigma surrounding infertility. As a result, many donor-conceived individuals were unaware that they had been conceived using donated sperm – the primary form of gamete donation at the time.

In recent decades, however, there has been a cultural and legal shift toward recognising the rights and interests of donor-conceived people. A key example of this is Victoria's decision in 2017 to grant universal access to donor-identifying information, regardless of when the donation occurred.

Currently in WA, only individuals conceived from gametes donated on or after 1 December 2004 have a legal right to access identifying information about their donor, beginning at age 16. For those born before this date, access is conditional on the donor's consent – if the information is available at all.

The Bill strengthens protections for donor-conceived people by expanding access to identifying donor information, regardless of when the person was born or when the donation occurred – subject to the availability of information. Additionally, it proposes including an addendum on birth certificates for donor-conceived individuals and those born through surrogacy. Once they reach age 16, this note will inform them that further information about their conception is available in the birth register. This model is already in place in Victoria.

#### Summary

Key changes in the Bill:

- Broader eligibility criteria, removing discriminatory barriers to accessing fertility treatment and surrogacy.
- A right for donor-conceived individuals to access information about their genetic heritage.
- Legal use of stored sperm, eggs or embryos after a partner's death, where clear consent has been given.
- Streamlined processes for PGT, including for tissue matching.
- Establishment of an Assisted Reproductive Technology Advisory and Review Board to oversee complex ethical approvals and provide guidance.

#### What this means in practice

Same sex couples, single individuals and genderdiverse people in WA will finally have equal access to IVF, reciprocal IVF and altruistic surrogacy in WA, without needing to travel interstate or overseas. It is important to note that commercial surrogacy remains illegal in Australia. However, under the new laws, the payment of reasonable expenses to a surrogate will be permitted.

These long-overdue reforms mark a major shift in WA's approach to reproductive rights and family formation. By aligning the law with current medical practices, social realties and national standards, WA is taking important steps toward equality, inclusion and autonomy in reproductive healthcare.

#### SPARKEBEAT SNAPSHOTS!



#### Title changes for podiatrists

From 5 October 2026, the title "podiatric surgeon" will be replaced with "surgical podiatrist". The title change aims to clarify roles for consumers and reduce confusion about qualifications and scope of practice, as the title "podiatric surgeon" suggested a medically trained surgeon. The change does not affect the standard of care, but is intended to improve transparency, patient safety and regulatory oversight. Podiatry practitioners have 12 months to adjust to their new titles.

#### Indexed maximum award for non-economic loss







#### Watch this space! Sexual misconduct and health practitioners

Watch this space – With submissions having closed on 6 October 2025, AHPRA is seeking to expand the information that is published on the public register about health practitioners who have engaged in professional misconduct involving sexual misconduct. Whilst the National Law does not currently define "sexual misconduct", under proposed changes to the National Law, the 15 National Boards for the 16 registered health professions will decide whether a Tribunal's finding of professional misconduct involves sexual misconduct (where such behaviours fall within the ordinary meaning of "sexual misconduct" – and when that determination is made, registered health practitioners who have been found to have engaged in sexual misconduct will have information about that conduct permanently recorded on the national register. The change is proposed to be retrospective.

#### Move to ban doulas from providing freebirths in Australia

The Australian College of Midwives and the Royal Australian and New Zealand College of Obstetricians and Gynaecologist have called on the Federal Government to bring state and territory legislation in line with South Australia to ban doulas from providing freebirths in Australia. It is an offence for any person in South Australia, other than a medical practitioner or midwife registered under s 123A of the Health Practitioner Regulation National Law, to carry out a restricted birthing practice.



This follows recent tragedies, such as the death of Melbourne influencer Stacey Hatfield, who died shortly after giving birth at home in September without a registered Midwife present. In South Australia, birth workers who perform restricted birthing practises can be fined up to \$30,000 or jailed for up to 12 months.

# RIGHTS, REMEDIES & REFORM - AN ANALYSIS OF THE NEW COMPENSATION PATHWAY IN THE NEW AGED CARE ACT 2024

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Author: Lani Carter (Special Counsel)
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After hearing harrowing stories of abuse and neglect in the aged care system, the Royal Commission into Aged Care Quality and Safety recommended a new compensation pathway for individuals who experience abuse, neglect, or substandard care.

The recommendation was ultimately<sup>1</sup> included in the new *Aged Care Act 2024* (Cth) (the **Act**), which will come into force on 1 November 2025.

#### What you need to know

The new pathway has several important implications:



1. It may reduce the financial and administrative burden on individuals seeking compensation by enabling the Commissioner to bring the action on their behalf (with their consent).



2. It could lead to efficiencies if civil penalty applications run concurrently with applications for compensation.



3. In some cases, this new pathway may effectively extend the limitation period for individuals to bring a claim. For instance, individuals might be out of time for a personal injury claim, but still eligible to bring a claim under the Act.



4. Due to these factors, the pathway may lead to an increase in claims; however, we do not expect this increase to be substantial, as it will depend on the resources allocated to the Commissioner to bring such claims.

<sup>1.</sup> The Commonwealth Government's response to the Royal Commission final report was published on 11 May 2021 noted that this recommendation was under consideration and would be considered as part of the drafting of the new Aged Care Act 2024 – it was ultimately included.

Our clients in the insurance and aged care sectors have been asking about the implications of the compensation pathway. This article anticipates how we expect it will work.

Section 186 of the Act provides for an additional pathway for aged care residents to receive compensation for *serious injury or illness* under the following conditions:

- a. The aged care entity is liable for a civil penalty for contravening ss 179(3) or (5).<sup>2</sup> These sections provide that an aged care provider, while delivering funded aged care services, is required to ensure its conduct does not cause adverse effects to the health and safety of those in care, as far as reasonable practicable.
- b. The serious injury or illness has resulted from the contravention.

It is important to note that claims under s 186 are limited to those *seeking compensation for serious illness or injury*, which individuals may already pursue through other means. The Act also separately provides for civil penalties, which are intended to punish and deter non-compliance. Therefore, it is not readily apparent what additional benefits or changes this new pathway introduces to the regulation of the aged care sector.

Serious injury or illness is defined to include:

- a. immediate treatment for:
  - i. the amputation of any part of the individual's body; or
  - ii. a serious head injury; or
  - iii. a serious eye injury; or
  - iv. a serious burn; or
  - v. the separation of the individual's skin from an underlying tissue (such as degloving or scalping); or
  - vi. a spinal injury; or
  - vii. the loss of a bodily function; or
  - viii. serious lacerations; or
  - ix. a serious wound or pressure injury; or

b. medical treatment within 48 hours of exposure to a substance.

Each of these injuries and circumstances could already be pursued by way of civil claim.

For a claimant to take this new route, they must first establish liability to a civil penalty. This means that the first hurdle for a claimant (or the Commissioner) seeking to pursue this option is to demonstrate that liability to a civil penalty exists.<sup>3</sup> Unless a civil penalty has already been imposed, a claimant must first establish:<sup>4</sup>

- a. the provider has a duty pursuant to s 179 of the Act (i.e., they receive funding for provision of services)
- b. the provider has breached that duty, without reasonable excuse, and
- c. the conduct amounts to a serious failure.

The conduct of a registered provider amounts to a serious failure if it exposes an individual, for whom a duty is owed, to a risk of death, serious injury or illness; and the conduct involves a significant failure or is part of a systematic pattern of conduct.

Once this has been established, a claimant must prove that the serious injury or illness related to their claim resulted from the provider's breach of duty.

At first glance, this hurdle is just as challenging as establishing duty, breach, causation, and loss to a civil standard in a personal injury claim.

The Commissioner, with the individual's consent, or the individual themselves may apply for the order.

Parties have six years to make a claim after the contravention occurs. In many states, the limitation period for bringing personal injury claim is three years from the date of discovering the injury.<sup>5</sup> This means that, in some cases, individuals may have available a longer timeframe to bring their claim than with an ordinary personal injury claim.

<sup>2.</sup> Section 179 of the Act provides that an aged care facility providing funded aged care services must ensure, so far as is reasonably practicable, that their conduct does not cause adverse effects to the health and safety of individuals to whom the provider is delivering services).

<sup>3.</sup> We read this to mean that the provider would be liable to a civil penalty – but a civil penalty does not need to have been imposed.

<sup>4.</sup> S 179 of the Act.

<sup>5.</sup> See s14 Limitation Act 2005 (WA), s5A(3) Limitation Act 1974 (TAS), s12 Limitation Act 1981 (NT), s5OC(1)(a) Limitation Act 1969 No 31 (NSW) (but see also s5OC(1)(b)), s11 Limitation of Actions Act 1974 (QLD), s27D(a) Limitations of Actions Act 1958 (VIC) (but see also s27D(b) (and ACT already has six years from the cause of action – see s16B Limitations Act 1985 (ACT)).

The compensation pathway is not intended to replace existing avenues for compensation for personal injury, and it is important to note that the Act provides that individuals cannot 'double dip' and receive compensation twice for the same injury.

#### Legislation with purpose

Commissioner Lewis noted in the Royal Commission Final Report that: 'There are no mechanisms under the aged care legislation by which people receiving aged care services who have been harmed as a result of substandard care can be compensated.'6

An example of where the Commission considered another pathway may have been useful was the MiCare Case Study. In that particular case, after an audit of the facility in question, it was found that the health or wellbeing of fourteen residents may have been placed at serious risk. Sanctions were imposed by the Commissioner, but they were unable under the existing law to ensure that those residents were compensated for that harm.<sup>7</sup>

It was observed that pursuing civil proceedings may not be feasible for individuals for financial reasons and due to the likely duration of the litigation process, which can take years to resolve. Additionally, the stress of litigation may prevent claims from being pursued, especially for individuals who are frail or cognitively impaired.<sup>8</sup>

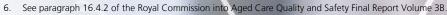
The new pathway aims to address these concerns by enabling the Commissioner to bring compensation proceedings on behalf of individuals, alleviating the administrative and financial burden they might face.

It may also be more efficient for the Commissioner to initiate these proceedings concurrently with applications for civil penalties.

The effectiveness of this new compensation pathway will largely depend on the resources the government allocates to the Commissioner to pursue compensation claims.



While the new pathway provides aged care residents with greater options for pursuing compensation and may extend the timeframe within which claims can be made, we consider the new pathway will be used sparingly and is unlikely to significantly increase the number of claims seen in this space.



<sup>7.</sup> Without the individuals bringing their own separate claims for personal injury.

<sup>8.</sup> See paragraph 16.4.2 of the Royal Commission into Aged Care Quality and Safety Final Report Volume 3B.





## AUSTRALIA'S HEALTHCARE SECTOR: A CYBERSECURITY FLASHPOINT

Authors: Jehan Mata (Partner) and Dinah Amrad (Associate)

Cyber threats in Australia's healthcare sector have reached unprecedented levels.

Recent reports from 2025 highlight a sharp rise in cyberattacks targeting sensitive patient data, including a 47% global surge in ransomware incidents in early 2025 and a 71% year-on-year increase in cyberattacks on the healthcare sector specifically. Australia ranks fifth worldwide in terms of exposure of internet-connected healthcare devices, with over 111,000 systems leaking sensitive data due to weak protections.

Recent breaches highlight the sector's vulnerability, such as the following breaches within Australia:

- MediSecure (April 2024): exposed prescription data of 12.9 million Australians.
- Women's & Children's Hospital, Adelaide (March 2025): ransomware compromised clinical notes of 2,200 patients.
- Genea IVF Clinic (February 2025): 700GB of patient data leaked to the dark web.

We have previously explored the evolving cyber landscape in our cyber compendium, Sparke Bytes, accessible via the following link: Sparke Bytes - June 2025: Sparke Helmore.

#### The evolving Legal and Regulatory Framework

In Australia, the long-anticipated second tranche of privacy law reforms is set to increase financial and regulatory risks linked to cyber incidents. The expected removal of the small business exemption under the *Privacy Act 1988*) will expand compliance obligations to thousands of previously exempt entities, reinforcing the critical role of cyber insurance in managing potential liabilities.

To date, the Medibank data breach in October 2022 remains one of the most consequential privacy incidents in Australian history, particularly for the healthcare sector. In brief, Medibank was targeted in a ransomware attack that compromised the personal and medical data of approximately 9.7 million individuals. The breach exposed critical information including Medicare numbers, passport details, and sensitive health records, much of which was later published on the dark web. This breach has triggered a series of legal and regulatory actions, as detailed below:

- The Office of the Australian Information Commissioner (OAIC) filed civil penalty proceedings against Medibank in the Federal Court, alleging that Medibank failed to take reasonable steps to protect the personal information it held. This marked the first time a regulator had taken such an action for a data breach in Australia.
- Multiple class actions have been filed, alleging Medibank failed to adequately protect customer data and lacked sufficient preventive measures, claiming breaches of privacy and information security, as well as misleading conduct.

- As an aside, the Medibank data breach has also resulted in an interlocutory issue relating to legal privilege (McClure v Medibank Private Limited [2025] FCA 167) where the Federal Court decision handed down in June 2025 found that reports where the legal purpose was not predominant could not be protected by legal professional privilege. This ruling impacted Medibank's ability to withhold these reports from the class action proceedings.
- Further, the Australian Prudential Regulation
   Authority expressed concerns about the strength
   of Medibank's operational controls and later
   increased its capital adequacy requirements due
   to issues with the company's information security
   environment. Medibank has also released
   findings from Deloitte's external review, which
   made recommendations for enhanced IT processes
   and systems. Medibank has begun to implement
   these recommendations.

Separately, in 2022, the Medlab Pathology data breach resulted in the exposure of personal and sensitive information including health records and Medicare card details, affecting approximately 223,000 customers.

On 30 September 2025, Australian Clinical Labs and the OAIC jointly submitted a proposed civil penalty of \$5.8 million to the Federal Court. This joint proposal remains subject to the Court's approval, with judgment currently reserved. The proposed penalty is broken down as follows:

- \$4.2 million for failing to take reasonable steps to protect the personal information of Medlab customers
- \$800,000 for contravening section 26WH(2) of the *Privacy Act*, which requires entities to assess whether there are reasonable grounds to believe a data breach has occurred, and
- \$800,000 for contravening section 26WK(2) of the *Privacy Act*, which requires entities to prepare a statement about a data breach as soon as reasonably practicable after becoming aware of it.

Considering the regulatory and legal responses triggered by the Medibank breach, the incident has become a catalyst for heightened scrutiny, particularly within the healthcare sector. Regulators such as the OAIC and the Australian Health Practitioner Regulation Agency (AHPRA) – the Agency that oversees practitioner conduct and patient confidentiality - are now placing increased emphasis on data security and cyber hygiene.

AHPRA for instance, is actively monitoring the cybersecurity practices of registered health professionals across disciplines, inter alia, doctors, nurses, pharmacists, psychologists and have indicated that it may investigate breaches, impose disciplinary measures, and scrutinise governance practices where poor data handling is evident.

As previously noted, the OAIC appears to be pursuing penalties for privacy breaches with a strong focus on the impact to affected individuals. Once the Federal Court makes a determination, it is expected to provide a precedent-setting rationale outlining the key factors considered in imposing punitive measures on Medibank and Medlab. This will likely include the scale of the breach, the sensitivity of the compromised data, and the adequacy of Medibank's/Medlab's preventative measures and response.

#### Key takeaways

#### For the insured / healthcare providers and for brokers

The implications for both the insured and the broker are closely interrelated, as outlined below.

The consequences for an insured, especially SMEs, are multi-faceted. From an operative perspective, breaches bring clinical operations to a halt. File management systems often go offline, forcing a manual workflow that strain staff and systems. Even temporary down time can lead to thousands of lost appointments and revenue. Separately, from a patient care perspective, there is breach of patient confidentiality, especially with the increase in the use of Artificial Intelligence, which leads to personal impacts on patients including stigma, embarrassment, and discrimination. The flow-on effect is the erosion of patient trust and ultimately, the patient-provider relationship.

For brokers, breaches in the healthcare sector presents significant opportunities and responsibilities. It involves not only educating business owners and practicing transparency in advising them about the potential issues and the financial impact of a cyber incident, but also helping

business owners to navigate the Australian cyber insurance market, including premium impacts and coverage and underwriting trends as well as practical advice on achieving the best renewal outcomes.

Specifically, brokers would need to advise on the extent of the policy inclusions, such as data breaches and system damage whether relevant to business owners, and that the policy also covers business interruptions and legal costs. Provision of other advice would include factors to consider when selecting an insurer such as industry experience, reputation, and financial stability as well as support services. Ultimately, it is about offering tailored solutions for health care providers, ensuring they have the right protection in place.



#### For the insurer

With the floodgates now open, the volume of such claims is expected to continue rising. The increase in claims coupled with the increasingly stringent responses from regulators means that insurers are experiencing escalating operational costs. These are driven by the need to invest in advanced technologies, expand cybersecurity teams, and strengthen incident response capabilities. Naturally, these costs are passed on to the insured, which further compels insurers to prioritise the reassessment of risk profiles and adjust premiums accordingly. Notably, healthcare providers that experience a cybersecurity breach often face substantial increases in their cyber liability insurance premiums, sometimes by 35% or more. Additionally, insurers may require organisations to undertake system upgrades or independent cybersecurity audits prior to policy renewal, further intensifying the financial impact.



#### Legal support as a pillar of effective cyber risk management

As lawyers specialising in cyber insurance and risk management, we are well equipped to provide the legal expertise necessary to efficiently triage cyber incidents. Our experience enables us to assess both indemnity issues and claims arising in this complex and rapidly evolving area.

This expertise is particularly valuable in the post-incident phase, where it is critical for insureds to conduct a thorough evaluation to identify lessons learned and implement appropriate improvements. Such evaluations should encompass both hard controls (e.g., technical safeguards) and soft controls (e.g., behavioural, and cultural responses), as well as an assessment of the insured's and third parties' actions during an incident. In this context, legal professionals play a pivotal role in coordinating a structured response that protects the insured's interests, mitigates exposure, and ensures compliance with their applicable privacy obligations.

## HIGH COURT REVISITS THE 'TOUCHSTONE OF REASONABLENESS'

Author: Mark Sainsbury (Partner)

In 1977, the High Court's decision in *Sharman v Evans* (1977) 138 CLR 563 established that a plaintiff's entitlement to damages for future medical care was to be guided by the "touchstone of reasonableness".

Almost 50 years later, the High Court's recent decision in *Stewart v Metro North Hospital and Health Service* [2025] HCA 34 confirmed the legal test for assessing the reasonableness of damages for future care, rejecting a cost-benefit approach in favour of a return to the fundamental tort law compensatory principle that an injured party is entitled to compensation for the sum that, so far as money can do, will put the plaintiff in the same position as they would have been if the tort had not been committed.

Tying these two cases together, the joint judgment of the High Court opens with the following paragraph:

The compensatory principle in tort entitles an injured party to compensation in a sum which, so far as money can do, will put that party in the same position as they would have been in if the tort had not been committed. In Sharman v Evans, 1 Gibbs and Stephen JJ referred to the "touchstone of reasonableness" when assessing compensation for a plaintiff's nursing and medical care following the negligence of a defendant. This appeal concerns reasonableness in the proof and assessment of loss where an injured party claims damages on the basis that they will or wish to live in their own home or in a home setting rather than in an institution or in an institutional setting.

#### **Background**

Michael Stewart was aged 63 when he sustained catastrophic injuries due to negligent medical treatment provided at Redcliffe Hospital in 2016 after presenting with nausea and generalised abdominal pain.

Metro North Hospital and Health Service (**MNHHS**) admitted liability for Mr Stewart's injuries that included bowel perforations, sepsis, cardiac arrest, stroke, and permanent brain damage. Mr Stewart was left with severe physical impairments, including paralysis of his right arm, contractures in his right leg, and aphasia. His life expectancy was assessed at five years at the time of trial.

Mr Stewart lived in a rented home with his brother in Margate, Queensland before the injury. He shared custody of his son with his ex-wife and kept family dogs. Post-injury, he was placed in institutional care at Ozanam Villa Aged Care Facility where he was unable to live with his son or dog. His physical condition deteriorated due to limited therapy and exercise.

Mr Stewart sought damages (via his ex-wife as litigation guardian) for future medical expenses for the costs of independent living in a rented private home, supported by medical and nursing care.

#### **Supreme Court trial**

Three options for Mr Stewart's future care for five years (his life expectancy) were considered by his Honour Justice Cooper at trial:

- 1. The cost of Mr Stewart's current care at Ozanam (\$304,605.46).
- 2. The cost of care at Ozanam with an external case assistant and the provision of more frequent therapy and exercise (\$1,081,895.56).
- 3. The cost for Mr Stewart to be cared for in his own rented home for the remainder of his life (\$4,910,342.52).

The trial judge accepted that Mr Stewart had clearly communicated his desire to live in his own home rather than at Ozanam, that additional care and therapy would result in improvements in Mr Stewart's physical and mental health, and that the provision of care and therapy to Mr Stewart in his own home, including the 'powerful motivator' of the presence of his son, would increase his willingness to engage in therapy.

Cooper J weighed the health benefits to Mr Stewart under the second and third options against the difference in their cost and concluded that the likely health benefits of the third option were not 'significantly better' than the second option.

His Honour concluded it was not reasonable to require MNHHS to pay the significant additional costs involved in Mr Stewart moving from Ozanam into his own home.

#### **Court of Appeal**

Mr Stewart appealed the trial judge's decision on the quantum of future care damages.

The Court of Appeal upheld the trial judge's reasoning and conclusion. It took a similar cost-benefit approach in determining whether the expenses for future care would be reasonably incurred and considered the difference in physical health benefits between the second and third options would be 'practically removed' by an increased level of engagement from Mr Stewart with the additional care and assistance provided by an external care assistant.

#### **High Court decision**

The High Court found that the lower courts had erred in their interpretation of 'reasonableness' by focusing too narrowly on a cost-to-benefit analysis of the Mr Stewart's ultimate health outcomes when assessing damages. In that regard, the Judges stated:

For the reasons explained above, the approach to reasonableness taken by the trial judge and the Court of Appeal, which reflected the approach adopted by some of the authorities decided after Sharman v Evans, \*\* was in error. The inquiry should have started from the premise that Mr Stewart was entitled to compensation in a sum which, as far as money can do, would put him in the same position as he would have been in had MNHHS not acted negligently. The inquiry should not have been reduced to a simple balancing of the costs to MNHHS and the health benefits to Mr Stewart of care at (a rented) home. In this case, the question was whether his choice to be eared for at home was a reasonable response to repair the consequences of the tort by MNHHS.

The High Court reaffirmed that damages ought to aim to return a plaintiff to the position they would have been in 'but for' the defendant's negligence, the Court asked whether Mr Stewart's decision to pursue homebased care constituted a 'reasonable' response to the harm he had suffered.

The Court articulated a two-stage framework for assessing 'reasonableness' in this context:

- **First**, the plaintiff must show that their chosen course of action was reasonably required to address the consequences of the injury.
- Second, if that threshold is met, the defendant must prove that the plaintiff acted unreasonably in declining a materially similar, less expensive alternative.

Applying this framework, the Court concluded that Mr Stewart's preference for home care was reasonable in the circumstances. Before suffering

the catastrophic injuries, he lived at home with his family, and returning to this environment offered a more authentic restoration of his pre-injury lifestyle than institutional care could and would provide. Additionally, the Court held that MNHHS had failed to discharge its burden of proving that Mr Stewart's rejection of institutional care was unreasonable.

The matter has been remitted to the Supreme Court of Queensland for reassessment of damages.

#### **Key points**



This decision marks a return to the fundamental principle of tort law that underpins compensatory damages: restitutio in integrum – restoration of the plaintiff's original condition as far as money or legal means allow, and the High Court has clearly rejected the cost-benefit approach of assessing reasonableness of compensation.

Defendants and their insurers will need to be alive to the potential for significantly increased awards of future care in personal injury claims that have circumstances permitting a reasonable argument for in-home care that will benefit a plaintiff both physically and mentally.

There is no doubt that plaintiff lawyers will seek to rely on the Stewart decision to justify increasing claims for home modifications, family-provided care, or private/at-home nursing. If a plaintiff is able to demonstrate that home care is reasonably required, the onus shifts to the defendant to prove that the plaintiff unreasonably refused an alternative option.

This case highlights the importance (when defending future cases) of obtaining adequate evidence to understand a plaintiff's pre-injury lifestyle (upon which any future care argument may be based) and obtaining appropriate expert medical and care evidence that may assist in proving a plaintiff's preferred care model is objectively unreasonable or that a cheaper alternative was unreasonably refused. The High Court has made it clear that cost comparisons alone will be inadequate.

## INQUEST INTO THE DEATH OF MRS MARGARET MARIANI

Authors: Marie-Clare Elder (Partner) and Sophie Whittaker (Law Graduate)

On 14 August 2025, Deputy State Coroner Baptie delivered her findings of the inquest into the death of Mrs Margaret Mariani (the **Inquest**). Mrs Mariani's death was referred to the Coroner for investigation, as her death was an unexpected consequence of the surgery she received.

#### The facts

On 22 May 2019, Mrs Mariani was admitted to Manning Base Hospital for conservative treatment of pancreatitis secondary to gallstones, complicated by respiratory failure and pulmonary oedema.

On 29 May 2019, her pancreatitis settled, and she was discharged home.

On 9 July 2019, Mrs Mariani attended a consultation with Dr Ghaly. Later that day, she also attended the pre-admission clinic. A Major Patient Alert Form was completed, which recorded her clinical alerts as including 'Morphine – Vomiting, Sulphur – Skin reaction (rash), Endone – nausea and vomiting'.

On 12 July 2019, Mrs Mariani attended Forster Private Hospital for a laparoscopic cholecystectomy, to be performed by Dr Ghaly. Mrs Mariani was admitted to the Day Surgery Unit at 12.30 pm and was transferred to the Operating Theatre at 2.04 pm. Her surgery commenced at 2.46 pm and concluded at 3.35 pm.

Following her surgery, Mrs Mariani was transferred to the Post-Anaesthesia Care Unit (**PACU**) at 3.36 pm. She was alert and breathing spontaneously. A Fentanyl Patient Controlled Analgesia (**PCA**) was commenced to manage her post-operative pain.

Whilst in the PACU, Mrs Mariani was instructed on the use of the PCA to manage her pain.

At 4.45 pm, Mrs Mariani was transferred to the ward, where her daughter was waiting. Mrs Mariani's daughter reported that her mother activated the PCA 'quite a number of times', which resulted in Mrs Mariani experiencing nausea. She also indicated that a nurse said, 'the button was pressed too many times', which had caused Mrs Mariani to feel sick.

At 10.28 pm, a progress note recorded that Mrs Mariani had vomited twice and had pressed the PCA button 11 times.

On 13 July 2019 at 1.30 am, EEN Bowden telephoned the on-call locum, Dr Mark Francis, and advised him of Mrs Mariani's condition. Dr Francis prescribed 4mg Dexamethasone for her nausea, and 50-100mg of Tramadol for her pain. Mrs Mariani appeared to settle after receiving the additional medications.

At 10.00 am, Ms Mariani's daughter asked Registered Nurse Lynette Martyn (**RN Martyn**) to call a doctor to examine her mother as she was in significant pain, however, no doctor attended.

Between 12.00pm and 1.00 pm, Mrs Mariani's daughter asked RN Martyn again to call a doctor to examine her mother. Dr Francis attended but no progress notes were taken to document this.

At 3.15 pm, Mrs Mariani's condition was recorded as deteriorating, with her oxygen saturation level at 84%, her blood pressure at 95/56 and a pulse rate of 108 bpm.

At 3.30 pm, a rapid response was called due to the significant and acute deterioration of her condition. An electrocardiogram and chest x-ray were performed. Dr Francis' differential diagnosis included possible sepsis with a respiratory source, a possible pulmonary embolism and possible sepsis from an abdominal source. Dr Francis arranged for an ambulance transfer to Manning Base Hospital.

At 4.31 pm, Mrs Mariani arrived at Manning Base Hospital. On arrival, a further CT scan was performed which indicated Mrs Mariani had vomited 500 mL of bilious vomit, which had aspirated into her lungs.

At 8.20 pm, Mrs Mariani was placed into palliative care.

On 14 July 2019 at 2.55 am, Mrs Mariani passed away in the Intensive Care Unit.

Ms Mariani's death was reported to the Coroner on 14 July 2019, as her death was classified as an unexpected consequence of her medical procedure.

#### Issues

Deputy State Coroner Baptie examined several keys questions, including:

- Whether the cholecystectomy surgery was performed with appropriate care and skill, how Ms Mariani's bowel perforations were caused and whether they ought to have been detected by the surgical team.
- 2. The appropriateness and adequacy of Mrs Mariani's post-operative care and treatment at Forster Private Hospital, including:
  - monitoring and documentation
  - timeliness of medical review
  - adequacy of responses to symptoms and deteriorations, and
  - systemic issues in hospital practices.

#### The findings

Deputy State Coroner Baptie found that Ms Mariani died from complications arising from cholecystectomy surgery.

Deputy State Coroner Baptie determined that the injury occasioned to Mrs Mariani during surgery was not as a result of Dr Ghaly or the surgical team's negligence, instead finding that the care and treatment Mrs Mariani received post-operatively was significantly deficient in numerous ways.

Deputy State Coroner Baptie determined that Mrs Mariani's death was a result of a steady deterioration in her physical presentation, in circumstances where there would have been signs of peritonitis present earlier than 3.15 pm on 13 July 2019 and where those signs were not recognised or escalated to the surgeon who performed the cholecystectomy surgery, impacting the provision of timely clinical care and treatment.

Deputy State Coroner Baptie found that if Mrs Mariani's symptoms, including her pain and discomfort, had been investigated at the request of her daughter on the morning of 13 July 2019, it is more likely than not that she could have been readmitted to theatre for a corrective procedure.

Deputy State Coroner Baptie concluded that Mrs Mariani's death was preventable, finding that the post-operative care she received at Forster Private Hospital was inadequate.

Deputy State Coroner Baptie determined that RN Martyn's monitoring of Mrs Mariani was 'grossly deficient' and likely negligent, particularly with regard to her lack of record keeping, which impacted the information available to both Dr Francis and Dr Ghaly. Deputy State Coroner Baptie specifically highlighted that Mrs Mariani's pain management charts were either not completed, partially completed or incorrectly completed, hampering communication to Dr Francis and Dr Ghaly regarding Ms Mariani's condition and the quality of her post-operative care.

Deputy State Coroner Baptie noted several systemic failures of Forster Private Hospital, which included:

- Poor, incomplete or inaccurate clinical records.
- Continued use of paper records and the inadequacy of biannual audits.
- Use of the PCA, the lack of documentation regarding the removal of the PCA and the supposed storage of the PCA containing unused Fentanyl for an unknown period.
- Confusing evidence regarding ongoing education and training of staff.
- Failure to implement a more appropriate orientation of locum practitioners.
- Lack of clarity of communication between VMOs and CMOs.



#### Recommendations

Pursuant to s 82 of the *Coroners Act 2009*, Deputy State Coroner Baptie recommended that Forster Private Hospital provide further training to all staff (including VMOs, CMOs/Locums and nursing staff) to ensure that the current policies and procedures are being adhered to with respect to documentation of patient's care.

Deputy State Coroner Baptie further recommended that Forster Private Hospital consider amending its policies and procedures to ensure that there is greater clarity regarding the expectations of a VMO being contacted by a CMO/Locum or nursing staff and in what circumstances.

Due to the public health and safety matters that arose on the available evidence, Deputy State Coroner Baptie recommended that a copy of the findings and the transcript of evidence be provided to the NSW Ministry of Health and the NSW Minister for Health and Minister for Regional Health for consideration.

Pursuant to s 151A(2) of the Health Practitioner Regulation National Law (NSW), Deputy State Coroner Baptie directed that a copy of the transcript of evidence be sent to the Health Care Complaints Commission and Nursing and Midwifery Board of Australia, requesting an examination of RN Martyn's conduct.



#### Implications for health providers

This inquest highlights the legal and clinical risks for hospitals where communication failures, inadequate record-keeping, and unclear escalation protocols compromise patient care. The findings emphasise the importance of accurate and contemporaneous clinical documentation, underscore the need for clear escalation pathways for treating specialists, and highlight the role training and systematic oversight play in preventing avoidable deaths.

# HEALTH CARE COMPLAINTS COMMISSION (NSW) V SHARIER: CASE NOTE REGARDING THE ADMINISTRATION OF AN OPIOID TO AN INFANT

Authors: Marie-Clare Elder (Partner) and Anthony Tsecagias (Paralegal)

Dr Mohammad Sharier (**Dr Sharier**), a medical practitioner based in Sydney, had his registration suspended for six months and received a fine of \$2,500 after he inadvertently administered oxycodone to a six-day old patient following a circumcision. It was found that Dr Sharier failed to advise the hospital as to his error and failed to provide the family with sufficient information to assess and address the issue. His actions cast a warning for medical practitioners who attempt to hide their mistakes, rather than reporting them honestly and transparently.

#### Incident – the administration of an opioid to an infant

Dr Sharier had been registered as a medical practitioner since March 2009 and became a fellow of the Royal Australian College of General Practitioners in 2025. He opened his own practice in March 2022. In March 2023, at around midday, Dr Sharier performed a circumcision on a six-day old patient (**Patient**), which was completed without issue. This was a procedure he had undertaken many times before.

Dr Sharier then provided the father of the Patient with what he believed to be a 0.5ml syringe of Children's Panadol. Instead the syringe contained 0.5ml of Oxycodone, an opioid used to relieve strong pain, which is highly addictive and commonly abused. It was found that the medication was stored unlabelled and incorrectly packaged, which led to the error.

The Patient's mother provided the medication to the Patient at home. Soon after, Dr Sharier called the Patient's father to advise him that the incorrect medication had been provided. Dr Sharier gave evidence that he provided an '...adult strong pain medication instead of infant Panadol,' and explained the effects of same. He explained that he was concerned the chemical names would not be understood by the Patient's father. Dr Sharier recommended the father take the Patient to the Liverpool Hospital for the antidote to reverse the effects of a likely opioid overdose. He also told the Patient's father to contact him via mobile. After performing a procedure on another patient, Dr Sharier had a missed call from the Patient's father.

The Patient's father stated that Dr Sharier did not advise them to take the Patient to the hospital and that they attempted to call Dr Sharier three times. He also stated that Dr Sharier advised the Patient was given "big kids Panadol" and was not given the medical name of the medication.

The Patient became very drowsy. Between the second and third call to Dr Sharier, the Patient's mother then contacted a midwife at Westmead Hospital who advised that they take the Patient to the Emergency Department of the nearest hospital. The midwife also asked the Patient's mother to obtain the specific name of the medication.

The Patient would not wake up and had difficulty breathing. His parents took him to Liverpool Hospital, where he was administered a drug to rapidly reverse the effects of an opioid overdose.

The Patient has since made a full recovery.

#### The hearing

Dr Sharier was prosecuted by the Health Care Complaints Commission (NSW) (HCCC) in the NSW Civil and Administrative Tribunal (**Tribunal**) on six grounds of complaint. All were found to be substantiated, with the exception of Ground 3(1) regarding the provision of a plastic syringe. The HCCC asserted that the Patient's parents ought to have been advised to purchase children's Panadol rather than use an unlabelled syringe being drawn up and provided by Dr Sharier. The Tribunal found there was no unsatisfactory professional conduct on this ground of complaint. The Tribunal found it was not unsatisfactory professional conduct as Dr Sharier's conduct did not 'significantly' fall below the standard expected of a practitioner of an equivalent

#### Level of training/experience.

The Tribunal found that:

- Dr Sharier had engaged in unsatisfactory professional conduct in that Dr Sharier was convicted of criminal offences in relation to this incident. Dr Sharier was charged under various clauses of the Poisons and Therapeutic Goods Regulation 2008 (NSW) and was convicted of the following offences on 17 August 2023:
  - supply of a poison that was not packaged in accordance with the Poisons Standard (clause 7(1)(a))
  - failure to correctly store a drug of addiction (clause 73(1)), and
  - failure to keep a drug register (clause 111(1)).
- Dr Sharier failed to, as required under s 130(1) of the Health Practitioner Regulation National Law 2009 (NSW), notify the National Board within seven days of being charged with the above offences.
- In relation to the HCCC complaint that Dr Sharier should not have provided an unlabelled syringe to the parents of the Patient and instead asked the parents to buy children's Panadol, the Tribunal found that although this practice was unusual, there was no unsatisfactory professional conduct and Dr Sharier's conduct did not 'significantly' fall below the standard expected of a practitioner of an equivalent level of training/experience.

Dr Sharier was found guilty of unsatisfactory professional conduct on the basis that he failed to:

- provide clear information as to the name and the dose of medication he had provided to the Patient's parents
- provided unsafe instructions to observe for symptoms and return to the clinic if necessary
- communicate the need for rapid transport to the hospital
- explain that an emergency opioid antidote could be administered at the hospital
- prioritise ongoing communication with the parents throughout the day
- contact the hospital to advise of the emergency
- provide a referral letter to the hospital including relevant clinical details
- maintain stock levels of oxycodone at the lowest practical level in patient care areas. In the past, he also inappropriately wrote two prescriptions for oxycodone, under a false and fictitious name, and
- maintain adequate or any records for the Patient, including an accurate birth history, weight, vital signs, the (mistaken) provision of oxycodone and any details of the conversations with the Patient's parents and any advice provided.

It was found that Dr Sharier's unsatisfactory professional conduct amounted to professional misconduct under s 139E of the National Law warranting suspension of his registration.

#### **Orders**

In the circumstances, the Tribunal made the following

- for the suspension of Dr Sharier's registration for a period of six months
- that Dr Sharier attend a six-month tailored education course
- that Dr Sharier complete a medical record audit within six months of expiration of the suspension, and
- a prohibition on Dr Sharier from possessing, supplying, manufacturing or dispensing any substance listed in Schedule 4D or Schedule 8 of the Poisons and Therapeutic Goods Regulation 2008 (NSW) or any substance in an equivalent list in any other Australian State or Territory.

After the suspension was complete, Dr Sharier was to practice under Category C Supervision and attend various meetings with a supervisor.

#### Lessons learnt

For medical practitioners, the key takeaways are:



When an inadvertent error has occurred, get on the 'front foot' by advising the person affected or their parent/guardian.



Keep thorough records of all communications with the person affected.



Ensure that thorough advice is provided as to the severity of the situation with full detail and direction as to the steps to be taken. Particularly, name important information correctly (such as medication names) to ensure the next practitioner has a full understanding of the situation.



Ensure that you are contactable as a priority, particularly in high-risk situations. Reception staff should be advised to contact you as a matter of urgency if the patient cannot reach you directly.



Obtain advice from trusted mentors, colleagues, insurer advice lines or professional associations to ensure you have not missed anything. Your judgement may be clouded and a second, unbiased opinion may assist in identifying and rectifying any potential issues.



Ensure compliance with the requirements for registering and storing drugs in accordance with the Uniform Poison Standard which operates across all jurisdictions as defined by the *Therapeutic Goods Act 1989* (Cth), being the *Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025* (Cth). In New South Wales, the relevant requirements are set under the *Poisons and Therapeutic Goods Act 2022 No 73* (NSW) and the *Poisons and Therapeutic Goods Regulation 2008* (NSW).<sup>1</sup>



Implement a process where compliance is periodically audited. A checklist for compliance may also be beneficial.

<sup>1.</sup> In Victoria, Drugs, Poisons and Controlled Substances Act 1981 (Vic) and Drugs, Poisons and Controlled Substances Regulations 2017 (Vic)

In South Australia, Controlled Substances Act 1984 (SA) and Controlled Substances (Poisons) Regulations 2011 (SA)

In Queensland, Medicines and Poisons Act 2019 (QLD) and Medicines and Poisons (Medicines) Regulation 2021 (QLD)

In Western Australia, Medicines and Poisons Act 2014 (WA) and Medicines and Poisons Regulations 2016 (WA)

In Tasmania, Poisons Act 1971 (Tas) and Poisons Regulations 2008 (Tas)

In the ACT, Medicines, Poisons and Therapeutic Goods Act 2008 (ACT) and Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT)

In the NT, Poisons and Therapeutic Goods Act 2002 (NT)

# CASE SUMMARY - OCCUPATIONAL THERAPIST SANCTIONED FOR BOUNDARY VIOLATIONS

Authors: Jehan Mata (Partner) and Fenella Selvaratnam (Paralegal)

#### Occupational Therapy Board of Australia v Oeldrich (Review and Regulation) [2025] VCAT 701

#### **Background**

In August 2025, the Victorian Civil and Administrative Tribunal (VCAT) determined disciplinary proceedings brought by the Occupational Therapy Board of Australia against occupational therapist, Naomi Oeldrich (Ms Oeldrich). The case arose following confidential notifications in 2021 that Ms Oeldrich had engaged in a sexual relationship with a client (Client A), who was a vulnerable participant in the National Disability Insurance Scheme (NDIS) with an acquired brain injury, a history of mental health conditions and drug dependency.

Client A began occupational therapy session with Ms Oeldrich in December 2019. Despite being aware of his vulnerabilities, Ms Oeldrich entered a personal relationship with him later that month, which developed into a sexual and intimate relationship by February 2020. The relationship continued for approximately 16 months, overlapping with her provision of therapy services until November 2020.



#### Issues

The issues for the tribunal to consider were:

- Whether the proven conduct amounted to professional misconduct under s 5 and 193 of the Health Practitioner Regulation National Law (Victoria) Act 2009.
- How Ms Oeldrich's conduct should be characterised considering professional standards, client vulnerability and community expectations.
- What sanctions should be sought to appropriately protect the public, deter similar conduct, and maintain trust in the profession.

#### **Tribunal findings**

It is not surprising that VCAT found Ms Oedlrich had engaged in serious professional misconduct by failing to maintain professional boundaries and exploiting the inherent power imbalance in the therapeutic relationship.

The tribunal had regard to:

- the vulnerability of Client A due to his acquired brain injury, psychiatric history and cognitive impairments
- the harm suffered by the client, including deterioration of mental health, job loss and loss of trust in health practitioners, and
- the protracted and secret nature of the relationship.

VCAT ordered that Ms Oeldrich be reprimanded and her registration as an occupational therapist be cancelled. She was disqualified from applying for registration for a period of 12 months following the Order.

#### Implications for insurers and healthcare professionals

In the making of the decision, VCAT highlighted the responsibility that healthcare professionals must have to promote the dignity, privacy, autonomy, and safety of their patients especially vulnerable clients.

From a risk management perspective, this is a timely reminder for insurers and healthcare professionals to continue to emphasise the importance of:



Ongoing education and training for health professionals on identifying, understanding and maintaining professional boundaries.



Clear policies and guidelines regarding practitioner-client relationships.



Prompt report and management of boundary concerns, crossings and violations to mitigate patient harm and to protect the integrity of the profession and the trust towards it from the community, including terminating any therapeutic relationships and appropriately transferring care of the patient.



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