

On the pulse - Top 10 health law issues to watch in 2019

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No ordinary consequence? Upcoming ACC appeal one to watch

If a treatment injury is an 'ordinary consequence of treatment' then ACC cover is not available – but what constitutes 'ordinary'? This is slated to be answered by the Court of Appeal this year, as ACC has been granted leave to appeal the High Court's decision in *Accident Compensation Corporation v Ng* (which related to three appeals of ACC decisions to decline treatment injury claims). A copy of the leave decision can be found [here](#).

In *ACC v Ng*, the High Court determined that ACC can only decline cover for injuries that are an 'ordinary consequence of treatment' if those injuries were more likely than not to occur. His Honour considered that he was giving effect to the purpose of the 2005 amendment to section 32 of the Accident Compensation Act 2001, removing the hard-edged statistical restriction of rarity from situations where an injured person might be entitled to cover, and the general obligation on the courts to interpret the Act in a generous and unrigidly way.

This shift has the potential to significantly increase access to ACC cover for patients who suffer an injury as a consequence of treatment. A corollary of that is that the burden of funding for the treatment and rehabilitation of those injuries will shift from DHBs to ACC, so we anticipate this appeal will attract keen interest from the health sector.

Systems reviews: Major changes ahead?

As the Government considers recommendations made as part of the Government Inquiry into Mental Health and Addiction (discussed in more detail below), two other reviews are underway that are also likely to result in significant recommendations for change; the health and disability system review, and the review into aged-care funding.

Health and disability system review

Announced in May 2018, the Minister of Health has described this as a major and wide-ranging review. It aims to identify potential changes to the health system in order to (among other things):

- Ensure accessibility and availability of health and disability services, and reduce disparities in health outcomes, particularly among Māori and Pacific peoples
- Deal with demographic changes, particularly New Zealand's growing and aging population
- Deal with environmental challenges, such as climate change and antibiotic resistance.

This review could result in recommendations for structural change. We expect this could include changes to the way services are funded and delivered, and changes to the role and number of DHBs. You can share your views via an [on-line survey](#) open from January to May 2019. An interim report to the Minister of Health is due in July 2019 (with a further opportunity for public submissions), and a final report by January 2020.

Aged-care funding review

This review is led by Ernst and Young and supported by a cross-sector steering group. It will consider whether the current funding model (under which DHBs pay a daily rate for each resident in an aged-care facility who is eligible for publicly funded care) is fit for purpose, given forecasts that the number of people residing in aged-care facilities will substantially increase and their needs will be more complex. The review will likely consider other issues facing the aged-care sector, such as the number and mix of facilities being built around New Zealand, and workforce issues including nursing vacancies.

Replacement medicines legislation – A script for change

In December 2018, the Government began consulting on a new Therapeutic Products Bill. The new Bill (which will replace the Medicines Act 1981) introduces a principles-based framework, with detail to be contained in Regulations and Rules. This approach is intended to help ensure currency as technology advances.

The regime will have a comprehensive process for approval of all therapeutic products and associated supply chain activities, from clinical trials and manufacturing, to prescribing and supply. Medical devices and cell and tissue products will be brought under the new approval regime.

In the pharmacy sector, the Bill proposes more flexibility in the licensing of pharmacy activities to allow supply of medicines away from specific pharmacy premises. It also proposes change to the current requirement that pharmacies be majority owned by pharmacists (intended to protect consumers from the risk of commercial interests overriding the professional judgement of pharmacists in the management and operation of pharmacies). The Bill proposes either strengthening or removing the majority ownership requirement but does not express a preference for either option, so this will be a key area for consultation and feedback.

Consultation closes on 18 April 2019. It is the start of a lengthy process involving further Government decision-making, the passage of the Bill into law, and then a further two year period to write the Regulations and Rules.

Controversial law reform: A therapeutic approach

2019 will see Parliament consider controversial law reform, including the possible decriminalisation of euthanasia and abortion, and an altered approach to use of controlled drugs. The purported rationale is to see a health services approach applied to these matters.

- **Euthanasia** – Having received over 35,000 submissions, the Justice Select Committee is currently preparing its report on the End of Life Choice Bill (due by 27 March 2019). The proposed law (as currently drafted) would give people with a terminal illness or a grievous and irremediable medical condition the option of requesting assisted dying. Significant issues have been raised regarding the Bill, and we expect a number of changes before its next reading in Parliament
- **Abortion** – Following Labour's election promise to review abortion laws, the Law Commission was tasked with providing advice on alternative options. The Commission has proposed three possible models: 1) permit women to make abortion decisions in consultation with their health practitioner (without any statutory test needing to be met); 2) amend the current statutory test, so that the health practitioner performing the abortion must reasonably believe it is appropriate in the circumstances (with regard to the woman's physical and mental health and wellbeing); or 3) a mixed model, with no statutory test prior to 22 weeks gestation, and the test at (2) for any later gestation. Looking ahead, Justice Minister Andrew Little is to present a paper to Cabinet on the matter this year
- **Controlled drugs** – The Government appears to be focused on facilitating access to healthcare services for drug users (eg proposed Misuse of Drugs Act amendments, which would give the Police a discretion as to whether or not to prosecute for possession / personal use of controlled drugs where a therapeutic approach would be more beneficial) while increasing criminal sanctions for drug manufacturers (eg the Psychoactive Substances Bill, which increases the penalty for supply and distribution of psychoactive substances). We also expect ongoing public attention on the Misuse of Drugs (Medicinal Cannabis) Amendment Act which took effect in December 2018.

Regulation of health practitioners – Updates to the HPCA Act on the way

In response to reviews of the Health Practitioners Competence Assurance Act in 2009 and 2012, an amendment Bill is likely to be passed this year. As currently drafted, the Bill includes:

- An express statement that it is the function of responsible authorities to receive and act on information from any person – including patients and members of the public – who raises concerns about the practice, conduct, or competence of a health practitioner
- New provisions for interim suspension of practising certificates on a without notice basis where the health practitioner is under investigation and there is a risk of serious harm to the public
- More discretion for responsible authorities in deciding how to deal with practitioners who have committed specified offences, including provision for the practitioner to undergo examination, treatment, counselling or therapy (with consent)
- A new ability for professional conduct committees to place conditions on a health practitioner's scope of practice (rather than recommending conditions to the responsible authority).

Breaking bad – Pharmacy price-fixing case and cartel crackdown on the horizon

In 2018, the Commerce Commission filed proceedings in relation to an alleged price fixing arrangement between pharmacies in Nelson. The Commission alleges that Prices Pharmacy 2011 Limited and its directors facilitated a price-fixing agreement with competing Nelson pharmacies, which (in most cases) resulted in an increase to the dispensing charge consumers paid for fully funded prescription items. This case will be one to watch in 2019, and indicates that cartel conduct continues to be a risk area for health sector organisations in New Zealand. This is of particular significance given that upcoming changes to the law (under the Commerce (Criminalisation of Cartels) Amendment Bill) will significantly increase the potential consequences for cartel conduct such as price fixing. The Bill is expected to be passed this year and provides for criminal liability for both individuals and companies (including imprisonment of up to seven years for individuals).

Although we expect that criminal charges for cartels will be rare, the Australian competition regulator has recently taken several cases under equivalent criminal provisions, including one where criminal charges have been laid against an Australian company, its managing director and a former employee for alleged cartel conduct relating to assistive technology products (eg wheelchairs and walking frames).

The Government is also currently consulting on potential changes to the misuse of market power prohibition in the Commerce Act. The proposed changes, if enacted, will mean that conduct of organisations with substantial market power will be assessed under a proposed new test which looks at whether conduct has the likely effect (or purpose) of substantially lessening competition in a market. Consultation on the proposal ends on 1 April 2019, following which proposals for legislative change are likely to be made.

Who ya gonna call? Policy clarification for accidents at work

Under the Health and Safety at Work Act 2015, persons conducting a business or undertaking (PCBUs), including DHBs and private health care providers, are required to tell WorkSafe about any notifiable events that arise from work.

The definition of 'notifiable event' is very broad, and there has been some confusion within the health sector about when notification to WorkSafe is required, noting that the health sector already has a range of checks and balances to address adverse events arising from the provision of medical treatment. While there is no statutory exception relating to health providers, WorkSafe issued a [policy clarification](#) in May 2018 and confirmed that:

- When a notifiable event arises from medical treatment administered by a registered health professional and is required to be notified through another regulatory process (for example, the Coroner), the PCBU does not need to notify WorkSafe as well (and WorkSafe will not take enforcement action against a PCBU for not notifying)
- Notifiable events arising out of non-clinical patient care, or resulting from the failure of equipment used in administering treatment, must still be notified to WorkSafe.

Since the release of the policy clarification, we have seen WorkSafe take a more active role in the health sector in areas in which it considers its jurisdiction to be appropriate. We are also seeing an increased focus by WorkSafe on workplace violence, bullying and mental health generally, and we expect this will continue to be a focus in 2019.

'Once in a generation' opportunity for mental health system reform

Following a year-long process that involved significant public and sector engagement, the Government Inquiry into Mental Health and Addiction released its report, **He Ara Oranga**, on 4 December last year. The report suggests major reform is needed across the sector (for an overview of the Inquiry's recommendations, see our [legal alert](#)).

Having campaigned heavily in relation to mental health, the Government has met with some criticism in terms of its approach to date. The decision to launch the Inquiry was controversial, with many suggesting urgent and meaningful change was required and that another review of the sector would not provide any new insights. After the release of He Ara Oranga, the Government established a Mental Health and Addiction Health Sector Leadership Group. This has since been replaced by a 'hub and spoke' model, with one central hub coordinated by the Ministry of Health and nine specialised groups tasked with tackling key Inquiry recommendations. This has again attracted negative comment about the length of time these working groups will take to agree upon actionable outcomes, which risks further delays to the implementation of much-needed reform.

Looking forward, we await the Government's formal response to He Ara Oranga later this month. We expect that mental health services reform will remain an important and contested issue in 2019.

Playing by the rules – ERA changes may affect health sector industrial action

The increase in industrial action in 2018 looks set to continue within the health sector during 2019. Employers will need to be conscious of their obligations in relation to collective bargaining, union rights, and strike action, particularly given the changes brought about by the Employment Relations Amendment Act 2018. A number of provisions from that Amendment Act came into

force on 5 December 2018, including in respect of:

- Union involvement, both in terms of collective bargaining and access to workplaces without prior employer consent
- Collective bargaining (employers can no longer choose to refuse to bargain for a multi-employer collective agreement)
- Strikes, both in terms of strike notices (which can no longer be invalidated by minor omissions or failures in technical requirements) and payment obligations for partial strikes (employers are no longer permitted to deduct pay in response to industrial action that is short of a total withdrawal of labour, as the partial strike pay deduction provisions in the Act have been repealed).

Further changes will come into force on 6 May 2019, including:

- Restoration of the duty to conclude bargaining unless there is a genuine and reasonable reason not to, and a requirement to keep bargaining on other matters even if there is a standstill / deadlock on another matter
- A requirement to include pay rates in collective agreements. Pay rates may include minimum rates or methods of calculation and must indicate how rates may change during the term.

Privacy remains an ongoing focus

Privacy concerns remained a global media focus in 2018, particularly due to the implementation of the European Union's General Data Protection Regulation (GDPR) in May, and the Cambridge Analytica scandal and subsequent investigation into Facebook's management of its users' data. We also saw difficult ethical issues arise in respect of the disclosure of health information, including novel negligence proceedings being issued against the St George's Healthcare NHS Trust for not informing a woman during her pregnancy that her father carried the gene for Huntington's disease (her father had refused consent to the disclosure).

We expect ongoing attention on privacy matters in 2019. Internationally, we have already seen an NZ\$85m fine imposed on Google in January for breach of the GDPR. Locally, the Justice Select Committee is due to report on the Privacy Bill in March this year (see our 2018 [update on the Privacy Bill](#)), and we will keep you updated on any amendments it recommends. We expect that changes to the Bill are likely, given the submissions the Committee has received and the ongoing international focus on privacy.

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