Russell Kennedy Lawyers

Health Bulletin 22 September 2021

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Russell Kennedy Alert: Update on electronic signatures

The rules regarding use of electronic signatures to sign agreements, deeds and other documents have been updated again. Russell Kennedy explores what this means for you and your business in its latest Corporate and Commercial alert.

If you are wondering whether you can sign documents electronically, please read here.

Russell Kennedy Health Alert: More changes to IVF legislation

Russell Kennedy recently published a Health Alert “More changes to IVF legislation from the Gorton Review”.

New amending legislation has been introduced into the Victorian Parliament to implement further recommendations arising from the Gorton Review into assisted reproductive treatment.

You can read the alert here.

TGA Alert: Rapid Antigen Tests Guidance

The Therapeutic Goods Administration (TGA) has published a guidance ahead of the introduction of rapid antigen testing into the Australian COVID-19 environment. The guidance is intended for businesses to understand how these tests can be used in their workplace, and includes a checklist to prepare businesses to deploy rapid antigen testing.

The TGA has recently approved a number rapid antigen tests for point-of-care use. This means that at this time, they are approved for use only by health practitioners and trained staff. Other conditions placed on the use of

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health practitioners and trained staff. Other conditions placed on the use of these tests include:

- There must be protocols in place to manage safety of the person performing the test and the person being tested, including PPE requirements;
- The health practitioner must be available to provide clinical advice regarding the outcome of the test where required; and
- Any state and territory requirements for COVID-19 testing of workers must be taken into consideration.

If your business is considering using rapid antigen tests, you can read the guidance here. The latest TGA guides are available on their website.

Development of a new PPE coaching app

A new app which aims to reduce the spread of COVID-19 and other infectious disease has been developed by Macquarie University's cardiothoracic surgeon Professor Michael Wilson and software developer Terry Carney from Futureantics.

Professor Wilson cited evidence that the biggest risk of a PPE breach in health professionals occurs when they remove (doff) contaminated PPE, a process that can involve 19 main steps. The app follows the US Centers for Disease Control and Prevention guidelines for correctly donning and doffing PPE which were developed in response to Ebola outbreaks.

The app identifies users through facial recognition, then guides them through the steps of the donning (putting on) or doffing (taking off) process, giving real-time feedback if there's a potential breach. Professor Wilson explained that the complex artificial intelligence behind the system immediately converts moving images from a webcam to mathematically represent someone putting a mask on their face, and then feeds the relevant information back; for example — 'You need to put your goggles on' or 'wash your hands for 20 seconds before going any further'.

Macquarie University trainee doctor Alexandra Zacharakis observed that "The AI-PPE system is like having a second pair of eyes watching you and making sure you don't miss anything; it's very reassuring, particularly if you've done a 12-hour shift and you're really tired."

To read more about the app, click here for Hospital Health's article, and here a copy of the US Centers for Disease Control and Prevention guidelines.

Poisons Standard scheduling changes for nicotine vaping products: implications for clinical practice

A change to the Poisons Standard due to commence from 1 October 2021 clarifies the regulation of nicotine for use in e-cigarettes as a Schedule 4 medicine.

Under the Poisons Standard, a Schedule 4 medicine is a "Prescription Only Medicine" meaning that the use or supply of such substances should be by or on the order of persons permitted by State or Territory legislation to prescribe, and should be available from a pharmacist on prescription. This means that Australians will require a prescription to legally access nicotine vaping products for any purpose.

The scheduling change covers the use of nicotine in e-cigarettes, e-juice, heat-not-burn tobacco products and other novel nicotine products. However, it will not affect other nicotine products such as sprays, patches, lozenges and gums.

The TGA Delegate that handed down the decision weighed up an extensive body of national and international research. This involved consideration of the use of nicotine vaping products to help people stop smoking but also the prevention of initiating nicotine addiction among non-smokers, particularly adolescents.

Medical practitioners will be able to seek authorisation from the Therapeutic Goods Administration (TGA) to be authorised prescribers.

There are three main application pathways. The Authorised Prescriber Scheme will allow prescription to any number of patients under a practitioner's care. The Special Access Scheme will allow access to nicotine vaping products for a single patient on a case-by-case basis. Lastly, the Personal Importation Scheme will allow patients to import nicotine vaping products with quantity restrictions.

The scheduling decision is in keeping with the RACGP's current guidelines on smoking cessation which state that nicotine vaping products are not recommended as first-line treatments for smoking cessation. However, they are a reasonable intervention for those who have unsuccessfully attempted to stop smoking with approved pharmacotherapies but still intend to quit.

This regulatory shift will spark increased opportunity for GPs to have conversations with patients about smoking cessation.

For further details on the scheduling decision and the relevant underlying research, see this NPS MedicineWise article.

How we can help

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