Health Legislation Amendment Regulation (No. 3) 2014

Explanatory notes for SL 2014 No. 201

made under the

Health Practitioners (Special Events Exemption) Act 1998
Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003
Tobacco and Other Smoking Products Act 1998

General Outline

Short title

Health Legislation Amendment Regulation (No. 3) 2014

Authorising law

Section 18 of the *Health Practitioners (Special Events Exemption) Act 1998*
Section 53 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*
Section 53 of the *Tobacco and Other Smoking Products Act 1998*

Policy objectives and the reasons for them

The policy objectives of the regulation are to:

- enable overseas health practitioners accompanying delegates to the Group of 20 (G20) Summit in Queensland to provide health services to those delegates without needing to be registered under health practitioner registration laws;
- ensure the references to prescribed guidelines for the purposes of issuing licences for research that involves the use of excess human embryos created through assisted reproductive technology are current; and
- reduce the regulatory burden on government and over 20,000 retailers by removing the need for mandatory signs to be distributed and replaced on an annual basis, and correct a typographical error.

G20 Summit

The *Health Practitioner Regulation National Law* requires health practitioners to be registered in order to provide health services in Queensland and throughout Australia. It is an offence under that law for a person to practise a regulated health profession without registration, or claim to be registered or qualified when they are not, and heavy penalties apply (currently $30,000 for an individual).

It is often the case with large sporting, cultural or political events ("special events") that delegations from other countries, who are participating in the event, are accompanied by a health team comprising health practitioners such as doctors, nurses, physiotherapists and psychologists ("visiting health practitioners"). The *Health Practitioners (Special Events Exemption) Act 1998* authorises visiting health practitioners to provide health care to the delegates they accompany to Queensland for the special event, without requiring them to register under the *Health Practitioner Regulation National Law*. This is achieved by prescribing the special event in regulation.

In September and November 2014, Queensland is hosting the G20 Summit in Cairns and Brisbane. Arrangements for the G20 Summit are being coordinated at a national level through the Commonwealth Government. The Department of Health has been advised that delegates from other countries will bring health care teams with them, and for this reason an amendment is required to prescribe the G20 Summit as a special event.

Prescribed guidelines for restricted research activities

Under a 2002 Council of Australian Governments (COAG) agreement, the Commonwealth, States and Territories have committed to nationally consistent legislation to ban human cloning and other unacceptable practices associated with reproductive technology, and to establish a national regulatory framework for the use of excess assisted reproductive technology embryos. COAG further agreed the regulatory regime for licensing of research involving excess assisted reproductive technology embryos would be administered by the National Health and Medical Research Council (NHMRC).

To give effect to this agreement, State and Territory legislation was introduced to complement the two pieces of Commonwealth legislation – the *Prohibition of Human Cloning Act 2002* (Cwlth) and *Research Involving Human Embryos Act 2002* (Cwlth). Due to Constitutional limitations, the Commonwealth Acts do not provide full regulatory coverage for ethical medical research involving embryos (for example, they do not cover the activities of State Government agencies, individuals or higher education institutions). Therefore, both State and Commonwealth legislation is required to provide full regulatory coverage.

The Queensland legislation – the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* – establishes a framework to prohibit certain unacceptable practices (such as human cloning) and regulate the use of excess human embryos created though assisted reproductive technology, other embryos and human eggs.

Under the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*, a person may apply to the NHMRC Licensing Committee for a licence to authorise restricted activities under the Act, such as the use of excess assisted reproductive technology embryos.

The *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* prescribes matters that must be considered by the NHMRC Licensing Committee when deciding whether or not to issue a licence. One of the matters the NHMRC Licensing Committee must have regard to is "any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC under the *National Health and Medical Research Council Act 1992* (Cwlth) and prescribed under a regulation".

The *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003* currently prescribes two guidelines issued by the NHMRC, as matters that must be taken into account by an NHMRC Licensing Committee when deciding whether to issue a licence. These guidelines are the:

- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, issued by the NHMRC in 2004; and
- National Statement on Ethical Conduct in Research Involving Humans, issued by the NHMRC in 1999.

Since prescribing these guidelines, they have been reviewed and remade or updated by the NHMRC to take into account changes in the complementary Commonwealth legislation. The revisions to these guidelines have resulted in a change to their titles. As such, amendments are required to update the references to these documents in the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003* to ensure they remain current.

Mandatory signs for retail supply of smoking products

The *Tobacco and Other Smoking Products Act 1998* prohibits the sale of tobacco and other smoking products to children. Retailers and persons in charge of a tobacco product vending machine are required to display a sign, prescribed under a regulation as a "mandatory sign", at the point of sale or on the vending machine.

The requirements for the mandatory sign are prescribed in the *Tobacco and Other Smoking Products Regulation 2010* and include the maximum penalty that applies for an offence of selling smoking products to a child. The prescribed maximum penalty is $42,000, which reflects the penalty amount in force at the time of imposing the mandatory sign. However, the penalty unit value increased in 2012 and is now indexed annually under the *Penalties and Sentences Act 1992*. Thus, the maximum penalty included on the mandatory sign is out of date, and will continue to be out of date each year when the penalty unit value is increased.

Specifying the maximum penalty was essential when the laws about supplying smoking products to children were introduced in 1998, as it was seen as a deterrent, similar to the approach taken for signs at licensed premises relating to responsible service of alcohol. However, the laws have been in place for such a long period of time now that it is no longer necessary to display a maximum penalty on the mandatory signs.

In addition, including the maximum penalty amount on the mandatory sign creates a regulatory burden for government and retailers across Queensland. It requires the Department of Health to amend the *Tobacco and Other Smoking Products Regulation 2010* each year, organise for the printing and supply of over 20,000 signs, and deploy a communication strategy to advise over 20,000 retailers of the new sign requirements. It also requires retailers and persons in charge of vending machines to replace the mandatory sign each year. Failure to display the mandatory sign, as prescribed, is an offence.

A further amendment to the *Tobacco and Other Smoking Products Regulation 2010* is proposed to address a typographical error, whereby the regulation refers to definitions used in the 'Act', rather than the 'Regulation'.

Achievement of policy objectives

G20 Summit

The regulation amends the *Health Practitioners (Special Events Exemption) Regulation 2009* to prescribe the G20 Summit as a 'special event'. The G20 Summit is defined by reference to the definition of this event in section 7 of the *G20 (Safety and Security) Act 2013*, in order to capture both the G20 Finance Ministers and Central Bank Governors meeting in Cairns on 20 and 21 September 2014 and the G20 Leaders Summit in Brisbane on 15 and 16 November 2014. The event is prescribed for the period 18 September 2014 to 17 November 2014, to cover the arrival and departure periods for delegates attending the event.

Prescribed guidelines for restricted research activities

The regulation amends the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003* to update the names of the guidelines currently prescribed in that regulation to refer to the:

- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, issued by the NHMRC; and
- National Statement on Ethical Conduct in Human Research, issued by the NHMRC.

The *Statutory Instruments Act 1992* provides that a regulation that applies or adopts the provisions of a document does so on the basis that the prescribed document is applied/adopted as in force from time to time, unless otherwise stated in the regulation. To ensure the prescribing of these documents meets the intent of the *Statutory Instruments Act 1992*, the reference to the year in which each of the documents was issued has been removed and an editor's note has been included to provide a hyperlink to the NHMRC website from where each of the guidelines may be downloaded.

Mandatory signs for retail supply of smoking products

The regulation amends the mandatory signage requirements in the *Tobacco and Other Smoking Products Regulation 2010* to remove the penalty amount and replace it with the text "Penalties apply". In addition, section 1A of the *Tobacco and Other Smoking Products Regulation 2010* is amended to refer to definitions used in the Regulation, rather than the Act.

As failure to display a sign that complies with the requirements prescribed in the *Tobacco and Other Smoking Products Regulation 2010* is an offence, and the Department has historically provided these signs to retailers free of charge, the regulation provides a transition period for retailers to update their mandatory sign to comply with the new requirements. This will provide sufficient time for the Department to communicate the changes and print new signs. Therefore, retailers and persons in charge of tobacco product vending machines will have until 30 June 2015 to comply with the new sign requirements, and will not commit an offence if they are found to display the current sign until that date.

Consistency with policy objectives of authorising law

The regulation is consistent with the main objectives of the *Health Practitioners (Special Events Exemption) Act 1998*, the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* and the *Tobacco and Other Smoking Products Act 1998*.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The regulation is not expected to impose financial or other costs on stakeholders. In the case of the amendments to the *Tobacco and Other Smoking Products Regulation 2010*, the removal of the maximum penalty from the mandatory sign will reduce regulatory burden and will avoid the minor cost on retailers and persons in charge of tobacco product vending from having to replace the mandatory sign each year. Further, the Department of Health has provided this sign free of charge to retailers, upon request, and will continue to do so. The cost of printing and supplying these new signs is approximately $20,000. While there will be an initial outlay to print and supply the new sign (with the maximum penalty removed), the ongoing annual cost of printing new signs is avoided.

Consistency with fundamental legislative principles

The regulation is consistent with fundamental legislative principles, as set out in section 4 of the *Legislative Standards Act 1992*.

Consultation

The Office of Best Practice Regulation was consulted on the regulation, in satisfaction of the requirements of the Regulatory Impact Statement (RIS) System. The Office of Best Practice Regulation advised that a RIS is not required. No further consultation was undertaken, as the amendments address operational or technical matters.

In regards to implementation of the signage requirements under the *Tobacco and Other Smoking Products Regulation 2010*, retailers and persons in charge of tobacco product vending machines will be advised of the new signage requirements (and the transitional arrangements) via retail and tobacco company networks.

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 provides the short title of the regulation.

Part 2 Amendment of Health Practitioners (Special Events Exemption) Regulation 2009

Regulation amended

Clause 2 specifies that this part amends the *Health Practitioners (Special Events Exemption) Regulation 2009*.

Replacement of s 2 (Declaration of Nikon SuperGP as special event)

Clause 3 amends section 2 of the *Health Practitioners (Special Events Exemption) Regulation 2009* to prescribe the G20 meeting and the associated exemption period.

The definition of 'G20 meeting' refers to section 7 of the *G20 (Safety and Security) Act 2013*, to ensure that the prescribing of the event captures both the G20 Finance Ministers and Central Bank Governors meeting in Cairns on 20 and 21 September 2014 and the G20 Leaders Summit in Brisbane on 15 and 16 November 2014, as well as other events associated with the G20 Summit.

The Nikon SuperGP, which is currently prescribed as a special event, is now redundant. Therefore, clause 3 also omits the Nikon SuperGP as a special event.

Part 3 Amendment of Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003

Regulation amended

Clause 4 specifies that this part amends the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003*.

Amendment of s 3 (Prescribed guidelines to which NHMRC Licensing Committee must have regard––Act, s 29)

Clause 5 amends sections 3(a) and 3(b) of the *Research Involving Human Embryos and Prohibition of Human Cloning Regulation 2003*.

The amendment to section 3(a) updates the title of the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* issued by the NHMRC, which is currently prescribed, to reflect changes made to that guideline as a result of amendments to Commonwealth legislation, and to ensure the prescribing of the document meets the intent of section 23 of the *Statutory Instruments Act 1992*.

The amendment to section 3(b) updates the title of the *National Statement on Ethical Conduct in Research Involving Humans* issued by the NHMRC, which is currently prescribed, to reflect changes made to that guideline as a result of amendments to Commonwealth legislation and a change in title to the *National Statement on Ethical Conduct in Human Research*, and to ensure the prescribing of the document meets the intent of section 23 of the *Statutory Instruments Act 1992*.

Part 4 Amendment of Tobacco and Other Smoking Products Regulation 2010

Regulation amended

Clause 6 specifies that this part amends the *Tobacco and Other Smoking Products Regulation 2010.*

Amendment of s 1A (Definitions)

Clause 7 amends section 1A of the *Tobacco and Other Smoking Products Regulation 2010* to correct a typographical error and refer to definitions used under the 'Regulation' rather than the 'Act'.

Amendment of s 8 (Form of mandatory sign––Act, ss 26HC and 26IF)

Clause 8 amends section 8(1)(b) of the *Tobacco and Other Smoking Products Regulation 2010* to remove the reference to the maximum penalty amount of $42,000 and prescribe a new requirement that the sign instead include the words 'Penalties apply'.

Insertion of new pt 7

Clause 9 inserts new part 7 and section 18 into the *Tobacco and Other Smoking Products Regulation 2010*. Part 7 provides for transitional provisions, and new section 18 provides a transitional provision for retailers to comply with the new mandatory sign requirement in clause 8.