Health Legislation Amendment Regulation (No. 3) 2015

Explanatory notes for SL 2015 No. 154

made under the

Health Act 1937
Mental Health Act 2000
Public Health Act 2005
Public Health (Infection Control for Personal Appearance Services) Act 2003
Tobacco and Other Smoking Products Act 1998

General Outline

Short title

Health Legislation Amendment Regulation (No. 3) 2015

Authorising law

Section 180 of the *Health Act 1937*
Section 545 of the *Mental Health Act 2000*
Section 461 of the *Public Health Act 2005*
Section 148 of the *Public Health (Infection Control for Personal Appearance Services) Act 2003*
Section 53 of the *Tobacco and Other Smoking Products Act 1998*

Policy objectives and the reasons for them

The objective of the *Health Legislation Amendment Regulation (No. 3) 2015* (the Regulation) is to amend:

- the *Health (Drugs and Poisons) Regulation 1996* (Health (Drugs and Poisons) Regulation) to:
  - provide greater treatment options through the use of nabiximols (Sativex™ - a patented cannabinoid oromucosal mouth spray) for Multiple Sclerosis patients throughout Queensland, to reduce the severity of their debilitating symptoms,
  - improve management of regulated poisons by including an as-of-right authority for the transport and delivery of regulated poisons by authorised carriers,

  - provide safe and effective disposal options of regulated poisons for authorised regulated poison holders, and
  - protect public health and warrant more stringent access controls to ensure that para-amino propriophenone is only obtained and used by authorised persons for specific purposes;
- the *Health Regulation 1996* (Health Regulation) to enable the facilitation of new approaches to human immunodeficiency virus (HIV) testing by allowing access to 'reagents', an essential chemical used to detect antibodies when testing for HIV;
- the *Mental Health Regulation 2002* (Mental Health Regulation) to:
  - ensure that the correct section of the *Mental Health Act 2000* (Mental Health Act) is referenced in relation to a requirement for the administrator of an authorised mental health service to keep records about involuntary inpatients, and
  - update the schedule of corresponding laws in the Mental Health Regulation which is outdated and incomplete due to legislative changes in other jurisdictions;
- the *Public Health (Infection Control for Personal Appearance Services) Regulation 2003* (Public Health (Infection Control for Personal Appearance Services) Regulation) to minimise the risk of infection arising from personal appearance services, by prescribing tattoo removal as a higher risk personal appearance service under the *Public Health (Infection Control for Personal Appearance Services) Act 2003* (Public Health (Infection Control for Personal Appearance Services) Act);
- the *Public Health Regulation 2005* (Public Health Regulation) to:
  - ensure that condition names and case definitions in schedules 1, 2 and 2A are consistent with contemporary terminology,
  - allow greater identification, management, reduction and if possible, elimination of lead exposure sources, by identifying persons who have lead exposure with blood lead levels of 5 µg/dL or more, and
  - enable greater public health action to limit the spread of measles by prescribing measles as a controlled notifiable condition; and
- the *Tobacco and Other Smoking Products Regulation 2010* (Tobacco and Other Smoking Products Regulation) to allow local councils in Townsville and Cairns to regulate smoking in their local area and enable them to enforce bans that prohibit smoking within four metres of an entrance to a public building.

Health (Drugs and Poisons) Regulation 1996

Medicines, poisons and other therapeutic substances are regulated in Queensland under the Health (Drugs and Poisons) Regulation. The aim of the Health (Drugs and Poisons) Regulation is to protect the public from the health risks associated with the inappropriate use of drugs, poisons and other therapeutic substances, and to minimise the risk of those substances being diverted for unlawful purposes.

The Health (Drugs and Poisons) Regulation confers an as-of-right authority (an endorsement) on specified health professionals to carry out particular activities (such as administering, prescribing, supplying etc.) with particular categories of drugs. These as-of-right authorities vary between different health professions, and are reflective of the qualifications, training and clinical experience of the relevant health practitioner to safely and appropriately use the

specified drugs and poisons. It is an offence for a person to perform an activity with a drug or poison if they are not authorised to do so.

The Health (Drugs and Poisons) Regulation classifies medicines, poisons and other therapeutic substances as controlled drugs, restricted drugs, or poisons. A controlled drug is a substance which is available for use, but requires restrictions in relation to manufacture, supply, distribution, possession, and use to reduce abuse, misuse and physical or psychological dependence. Morphine is an example of a controlled drug.

Restricted drugs are substances which are only available on a prescription. Amoxycillin, a common antibiotic, is an example of a restricted drug.

'Poison' captures a range of other regulated substances, classified according to the level of harm to health they pose, from paracetamol, for example, to cyanide. Different classes of poisons require different levels of restrictions in relation to their availability, packaging, and manufacture.

People who are authorised to perform stated acts with controlled drugs, restricted drugs or poisons are called an 'authorised person' under the Health (Drugs and Poisons) Regulation.

Nabiximols (Sativex™)

The objective of the *Health Act 1937* (Health Act) is to protect the public and allow the delivery of health services and other activities relating to drugs and poisons to be undertaken effectively and efficiently.

In accordance with the objective of the Health Act, the Regulation will provide greater treatment options through the use of nabiximols (Sativex™ – a patented cannabinoid oromucosal mouth spray) for Multiple Sclerosis patients throughout Queensland to reduce the severity of their debilitating symptoms.

Multiple Sclerosis affects more than 1.2 million people worldwide, including 23,700 Australians. Muscle spasticity is one of the most significant symptoms of Multiple Sclerosis, affecting up to 84 percent of patients and therapeutic options are currently limited. It can however be controlled with appropriate treatment determined by a team of health specialists.

The Poisons Standard consists of decisions regarding the classification of medicines and poisons into nine different schedules, signifying the degree of control recommended to be exercised over their availability to the public. The schedules are also developed for inclusion in the relevant legislation of the States and Territories.

In Queensland, the Health (Drugs and Poisons) Regulation regulates the use of scheduled drugs and medicines and outlines the particular authorities related to each class of health practitioner and the licensing and approval requirements for appropriate use of, and ability to access these drugs and medicines. The Health (Drugs and Poisons) Regulation automatically adopts medicines listed in schedule 8 of the Poisons Standard, however, does not automatically adopt medicines listed in schedule 8 with additional restrictions as described in Appendix D of the Poisons Standard. As a result, nabiximols (Sativex™) are currently not available as a treatment option for Multiple Sclerosis patients in Queensland.

Sativex™ has recently been registered for use for people with Multiple Sclerosis with muscle spasticity by the Therapeutic Goods Administration. Due to the nature of the medication, a change to the Health (Drugs and Poisons) Regulation is required before Sativex™ can be prescribed to patients in Queensland.

It is important to note that nabiximols contain cannabinoids tetrahydrocannabinol (THC) and cannabidiol (CBD) similar to, and a specific extract of the illicit drug cannabis. The amendment will allow Sativex™ to be recognised as a therapeutic preparation as a 'regulated controlled drug' to recognise its listing in Appendix D of the Poisons Standard.

The Health (Drugs and Poisons) Regulation is to be amended as a consequence to national changes to the Poisons Standard, which reschedules nabiximols from paragraph 3 of Appendix D to paragraph 1 of Appendix D, thus making it available only from or on the prescription or order of an authorised specialist health practitioner.

Transport and delivery of regulated poisons

By definition under the Health (Drugs and Poisons) Regulation, each transport company must be individually approved by the chief executive to possess regulated poisons for the purpose of transport and delivery.

Dangerous goods carriers are licensed under *Transport Operations (Road Use Management) Act 1995* and have appropriate training and skills to safely transport poisons. This includes mechanisms for tracking through consignment documentation to ensure the poison is not diverted for illegal purposes.

An inconsistency exists relating to the transport of regulated poisons, which does not meet the intent of the Health (Drugs and Poisons) Regulation. The Health (Drugs and Poisons) Regulation contains an as-of-right authority for carriers to the extent necessary to transport and deliver controlled drugs and restricted drugs. There is however, no as-of-right authority provided for the transport of regulated poisons by authorised carriers.

An amendment is required to authorise transport companies to transport and deliver regulated poisons. This amendment will result in improved management of regulated poisons, as transport carriers will be afforded an exemption provision that negates the need to seek endorsement from the Department of Health to transport and deliver regulated poisons.

Disposal of regulated poisons

The Health (Drugs and Poisons) Regulation provides that only a state analyst or a person in charge of a forensic and scientific facility is permitted to destroy a regulated poison while performing official duties. Additionally, a public health service employee employed by a Hospital and Health Service who obtains or possesses a regulated poison, may make arrangements for the destruction of the poison in a way authorised by the chief executive.

The Health (Drugs and Poisons) Regulation limits the options for approval holders to dispose of any unused/unwanted regulated poisons. The Regulation provides that approval holders seeking to dispose of or destroy poisons must also hold an approval to dispose/destroy poisons. Once the Regulation is made, an assessment will be carried out on a case by case basis to ensure the disposal/destruction of the poisons is undertaken in a manner that does not pose a risk to health or the environment.

An amendment is required to improve management and provide safe and effective disposal options of regulated poisons, such as disposal to approved land fill sites, deep burial in appropriate locations, and incineration at approved facilities. The amendment will further decrease public health risks as the potential hoarding of unused/unwanted regulated poisons is lessened due to greater approved disposal options.

Prescribe para-amino propriophenone

The Health (Drugs and Poisons) Regulation provides the access control framework for certain agricultural products such as strychnine and fluoroacetic acid which have been declared by the *Agricultural and Veterinary Chemicals Code Act 1994* as Restricted Chemical Products.

Appendix 7 of the Health (Drugs and Poisons) Regulation specifies poisons which have been classified as a regulated poison. These poisons are of sufficient danger to public health to warrant more stringent access controls to ensure they are only obtained and used by authorised persons for specific purposes.

Para-amino propiophenone is a new poison which has been developed for the purpose of animal baiting and has recently been proposed for inclusion in the Poisons Standard as a high risk schedule 7 poison.

The Department of Agriculture and Fisheries has advised its intention to have para-amino propiophenone declared as a Restricted Chemical Products in accordance with the *Agricultural and Veterinary Chemicals Code Regulation 1995*, to limit its use to only those persons who are appropriately trained.

Amendments are required to include para-amino propiophenone under Appendix 7 of the Health (Drugs and Poisons) Regulation, which will ensure consistency with scheduling requirements and with the established controls of other animal baiting poisons such as fluoroacetic acid (1080).

Health Regulation 1996

HIV testing

The Health Regulation restricts the sale, supply and use of a ‘reagent’, an essential chemical used to detect antibodies when testing for HIV, unless the reagent is being sold, supplied and used at an approved hospital or laboratory.

Australia has built a highly successful response to HIV, based on partnership and community mobilisation, resulting in relatively low rates of infection. While Australia is experiencing an increasing trend in new infections, we are seeing the rates stabilising in 2015. In 2014, there were 245 cases of HIV infection newly diagnosed in Queensland, which was the highest number recorded although to date, 2015 rates appear to be at similar levels to 2013.

There are many Australians who do not know that they have HIV, so efforts to improve testing and therefore diagnosis and linkage to treatment, care and support are crucial. It is estimated that there is an overall average of 3.4 years between infection and diagnosis, which can delay the commencement of treatment and potential increase onward transmission of HIV.

In 2012, the Therapeutic Goods Administration, Australia's regulatory authority responsible for regulating medicines, medical devices, gene technology and blood products, registered the first HIV rapid point-of-care test for use in non-laboratory settings. This has enabled the introduction of rapid point-of-care testing in community-based healthcare settings such as sexual health clinics as well as general practice, community-based settings and associated outreach locations, thereby increasing options for priority populations to access HIV testing.

An amendment to the Health Regulation is required to allow the sale, supply and use of a 'reagent', which will allow the facilitation of new approaches to HIV testing such as rapid point-of-care testing and home-based testing. Self-testing helps people overcome some common barriers to testing including access and acceptability issues, convenience and concerns regarding privacy and confidentiality. It is further expected that any additional methods of HIV testing have the potential to improve testing rates and lead to earlier diagnosis, intervention and better health outcomes through treatment and support.

Mental Health Regulation 2002

Records

The Mental Health Act provides for the involuntary assessment and treatment, and the protection, of persons (whether adults or minors) who have mental illnesses while at the same time safeguarding their rights and freedoms; and balancing their rights and freedoms with the rights and freedoms of other persons.

Section 545 of the Mental Health Act provides for the making of regulations for the keeping and inspection of records for involuntary patients of an authorised mental health service. Section 5(1) of the Mental Health Regulation provides that the administrator of an authorised mental health service must keep a record about each patient authorised under the Mental Health Act to be kept in seclusion in a health service.

Section 5(1) of the Mental Health Regulation refers to section 150 of the Mental Health Act as being the authorising provision for this section. However, section 150 was renumbered to 162L following amendments to the Mental Health Act under the *Forensic Disability Act 2011*.

An amendment to the Mental Health Regulation is required to change the reference to section 150 of the Mental Health Act to section 162L.

Corresponding laws

Under Chapter 5, Part 2 of the Mental Health Act, the Minister may, in accordance with section 176 of the Mental Health Act, enter into an agreement with another State about:

- the application of mental health related laws (corresponding laws) of Queensland or the other State,
- the transfer, detention and apprehension of persons in Queensland and the other State under mental health laws, and
- administrative and other matters incidental to such matters.

Interstate agreements require the declaration of corresponding laws in the Mental Health Regulation in order for provision under Chapter 5, Part 2 of the Mental Health Act to take effect.

Since commencement of the Mental Health Regulation in 2002, there have been changes to the corresponding interstate laws, including the passing of new mental health legislation in South Australia, New South Wales, Tasmania and Victoria and a change to the name of the mental health legislation in Western Australia.

Furthermore, mental health laws in New South Wales and Victoria relating to forensic patients (such as the *Mental Health (Forensic Provisions) Act 1990* (NSW) and the *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (Vic)) are not currently prescribed in the schedule to the Mental Health Regulation as corresponding laws. Forensic interstate agreements cannot formally be made between Queensland, New South Wales and Victoria until these corresponding laws are declared in the Mental Health Regulation.

An amendment to the Mental Health Regulation is required to update the schedule of corresponding laws which is out of date and incomplete due to legislative changes in other jurisdictions.

Public Health (Infection Control for Personal Appearance Services) Regulation 2003

Tattoo removal

The personal appearance service industry, which includes services such as body piercing and tattooing, is regulated under the Public Health (Infection Control for Personal Appearance Services) Act. The purpose of the Public Health (Infection Control for Personal Appearance Services) Act is to minimise the risk of infection that may result from the provision of personal appearance services.

To achieve this purpose, the Department of Health has a number of safeguards in place to ensure businesses offering high risk personal appearance services comply with strict hygiene and safety rules. The Public Health (Infection Control for Personal Appearance Services) Act provides for compliance with these rules to be monitored and enforced.

The Public Health (Infection Control for Personal Appearance Services) Act defines the meaning of a higher risk personal appearance service as any of the following skin penetration procedures in which the release of blood or other bodily fluid is an expected result:

- body piercing,
- implanting natural or synthetic substances into a person’s skin, including, for example, hair or beads,
- scarring or cutting a person’s skin using a sharp instrument to make a permanent mark, pattern or design,
- tattooing, and
- another skin penetration procedure prescribed under a regulation.

The Public Health (Infection Control for Personal Appearance Services) Act goes on to define skin penetration as a procedure intended to alter or enhance a person's appearance that involves the piercing, cutting, scarring, scraping, puncturing, or tearing of a person's skin or mucous membrane with an instrument.

The tattooist and tattoo removal industry is growing, and as a result there is an emerging and immediate public safety risk from the inappropriate and/or unlawful use of local or imported injectable tattoo removal products, sourced readily by business or individual consumers through local or international sites on the internet.

Practices such as tattoo removal involve significant risks to consumers when carried out with inappropriate equipment or products and service providers who are untrained and unlicensed. These risks include the potential for infection and the spread of communicable diseases such as hepatitis C as well as other adverse outcomes including burns, scarring, permanent eye damage, allergic skin reactions and hyper/hypo pigmentation of skin.

An amendment to the Public Health (Infection Control for Personal Appearance Services) Regulation is required prescribe tattoo removal as a higher risk personal appearance service under section 14 of the Public Health (Infection Control for Personal Appearance Services) Act. The amendment aims to protect public safety through minimising the risk of infection and communicable disease. Businesses providing tattoo removal services by the use of liquid containing injectable products are to be licenced and possess appropriate infection control qualifications. For the purposes of this amendment, it is important to note that tattoo removal does not involve the use of a laser, which could be construed as a skin penetration procedure.

Public Health Regulation 2005

Notifiable conditions

The *Public Health Act 2005* (Public Health Act) provides for a medical condition to be prescribed as a notifiable condition under regulation. The provisions of the Public Health Regulation provide the mechanisms for the prevention and control of notifiable conditions, maintaining an appropriate balance between the health of the public and the right of individuals to liberty and privacy.

Schedule 1 of the Public Health Regulation specifies the notifiable conditions and details when a person's condition should be notified to Queensland Health. Schedule 2 of the Public Health Regulation outlines those conditions which must be notified to Queensland Health immediately by doctors or laboratories. Generally, these conditions pose a significant public health risk and immediate public health interventions are required to limit spread of infection. Schedule 2A, Part 1 of the Public Health Regulation outlines a number of contagious conditions and prescribed periods that a child suspected of having the condition is required to stay away from school and child care.

Periodic changes are made to the notifiable conditions register to reflect new information, best practice guidelines and consultation with Queensland's public health system, health professionals and related agencies. As a result, amendments are required to ensure that condition names and case definitions in schedules 1, 2 and 2A are consistent with contemporary terminology.

Blood lead level

Lead exposure is currently listed in schedule 1 of the Public Health Regulation as a notifiable condition for blood lead levels of 10µg/dL (0.48µmol/L) or more. This means that, when laboratory testing of a blood sample indicates that it contains lead above the notifiable level, the details of the affected person and the test result must be provided to the Department of Health. This notification triggers a public health response to investigate and identify the source of the exposure.

The National Health and Medical Research Council (NHMRC), Australia's peak health body promoting health standards for the public and individuals, recommends that information be provided to the public of what can be regarded as above background exposure. Although NHMRC has not identified a strong link between low level exposure (blood lead levels between 5 ug/dL and 10 ug/dL) and adverse health effects, it has identified that the background lead levels (and therefore human exposures) are diminishing as the prevalence of lead use declines. Therefore a blood lead level of greater than 5 ug/dL is now the benchmark that indicates higher than background exposure.

An amendment to the Public Health Regulation is required to change the notification level for lead exposure (blood lead levels) from 10 ug/dL (0.48umol/L) to 5 ug/dL (0.24umol/L) or more. As a result of this revision, laboratories will be required to notify results that indicate a blood lead level of 5 ug/dL (0.24umol/L) and above.

The objective of the intervention is to identify persons who have lead exposure higher than background levels to allow greater identification, management, reduction and if possible, elimination of lead exposure sources. This will ensure that potential adverse health effects are better managed.

Measles

The objective of the Public Health Act is to protect and promote the health of the Queensland public. Provisions for achieving this objective include preventing, controlling and reducing risks to public health and providing for the identification of, and response to, notifiable conditions. The protection of the Queensland public must be achieved whilst also taking into consideration the right of individuals to liberty and privacy.

Various categories of notifiable conditions are defined in the Public Health Act and prescribed in the Public Health Regulation. Conditions prescribed under these categories have been determined to pose a significant risk to public health.

Measles has fulfilled this criterion and is currently prescribed as a pathological diagnosis notifiable condition and a provisional diagnosis notifiable condition in schedule 1 of the Public Health Regulation. Measles is also listed in schedule 2 of the Public Health Regulation as a condition requiring immediate notification.

Where a notifiable condition meets all of the following criteria, there is scope to additionally prescribe the condition as a 'controlled notifiable condition' under the Public Health Regulation:

- the condition may have a substantial impact on public health,

- the ordinary conduct of a person with the condition is likely to result in the transmission of the condition to someone else, and
- the transmission of the condition will result in, or is likely to result in, long term or serious deleterious consequences for the health of the persons to whom the condition is transmitted.

An amendment to the Public Health Regulation is required to declare measles as a 'controlled notifiable condition'. A number of infectious diseases are currently declared this way including avian influenza and smallpox.

Tobacco and Other Smoking Products Regulation 2010

Pedestrian malls

The *Tobacco and Other Smoking Products Act 1998* (Tobacco and Other Smoking Products Act) provides for the restriction of the supply of tobacco and other smoking products to children; the restriction of advertising and promotion of tobacco and other smoking products; and the prohibition of smoking in certain places including outdoor pedestrian malls.

In January 2005, the Tobacco and Other Smoking Products Act was amended to provide an exemption from the smoking ban within four metres of an entrance to public building or outdoor pedestrian malls that are prescribed under regulation. Local governments are responsible for enforcing the laws that ban smoking at outdoor pedestrian malls.

Of the malls prescribed in schedule 2 of the Tobacco and Other Smoking Products Regulation, those located in Townsville and Cairns have been subject to town planning redevelopment and beautification programs and are no longer classified by their local council as being an outdoor pedestrian mall.

The removal of the malls from the schedule will allow local councils in Townsville and Cairns to regulate smoking in their local area and enable them to enforce bans that prohibit smoking within four metres of an entrance to a public building.

Achievement of policy objectives

Health (Drugs and Poisons) Regulation 1996

Nabiximols (Sativex™)

The Regulation inserts new section 78A into the Health (Drugs and Poisons) Regulation to allow specialist health practitioners to dispense, prescribe, sell and use nabiximols for human therapeutic use.

Specialist health practitioners will include those working in the following specialities:

- the specialty of neurology or rehabilitation medicine, and
- registrars in neurology or rehabilitation medicine working directly under the supervision of specialist health practitioners in the speciality of neurology or rehabilitation medicine.

Transport and delivery of regulated poisons

To achieve this policy objective the Regulation inserts new section 273 into the Health (Drugs and Poisons) Regulation to include an as-of-right authority provision to allow authorised carriers to transport and deliver regulated poisons.

As a consequence of the above amendment, the Regulation further amends sections 55 and 158 (Carriers) of the Health (Drugs and Poisons) Regulation to specify that only a person engaged by an authorised person may transport and deliver a controlled or restricted drug.

Destroy or dispose of unused/unwanted regulated poisons

The Regulation amends section 271 of the Health (Drugs and Poisons) Regulation to permit authorised regulated poison holders to be issued with an approval to destroy or dispose of unused/unwanted quantities of regulated poisons.

Prescribing para-amino propiophenone

The Regulation includes para-amino propiophenone in item 7, Appendix 7 of the Health (Drugs and Poisons) Regulation so that only persons authorised under the Health (Drugs and Poisons) Regulation can use the poison for pest animal control.

Health Regulation 1996

HIV testing

To achieve the policy objective the Regulation removes section 179 of the Health Regulation to allow the sale, supply and use of a 'reagent', which will allow the facilitation of new approaches to HIV testing such as rapid point-of-care testing and home-based testing.

Mental Health Regulation 2002

Records

The Regulation will amend section 5(1) of the Mental Health Regulation to reference the correct section of the Mental Health Act, in relation to a requirement for the administrator of an authorised mental health service to keep records about involuntary inpatients.

Corresponding laws

The Regulation will amend the schedule of corresponding laws in the Mental Health Regulation to include all of the corresponding laws under agreement with another State, subject to section 176 of the Mental Health Act.

Public Health (Infection Control for Personal Appearance Services) Regulation 2003

Tattoo removal

To achieve this policy objective the Regulation inserts new section 5 into the Public Health (Infection Control for Personal Appearance Services) Regulation to prescribe tattoo removal as a high risk personal appearance service under section 14 of the Public Health (Infection

Control for Personal Appearance Services) Act. Prescribing tattoo removal under the Public Health (Infection Control for Personal Appearance Services) Act will require businesses providing such services to be licenced and possess appropriate infection control qualifications.

Public Health Regulation 2005

Notifiable conditions

The Regulation will amend schedules 1, 2 and 2A of the Public Health Regulation to ensure that all condition names and case definitions are consistent with contemporary terminology.

Blood lead level

The Regulation will amend schedule 1 of the Public Health Regulation to change the notification level for lead exposure, blood lead level, from 10 ug/dL (0.48umol/L) to 5 ug/dL (0.24umol/L) or more, to allow greater identification, management, reduction and if possible, elimination of lead exposure sources.

Measles

The Regulation will amend schedule 1 of the Public Health Regulation to prescribe measles as a 'controlled notifiable condition', to provide greater enforcement options to prevent widespread infection to the wider population.

Tobacco and Other Smoking Products Regulation 2010

Pedestrian malls

The Regulation amends schedule 2 of the Tobacco and Other Smoking Products Regulation to remove all references to prescribed outdoor pedestrian malls located in Townsville and Cairns.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the *Health Act 1937, Mental Health Act 2000, Public Health Act 2005, Public Health (Infection Control for Personal Appearance Services) Act 2003, and 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

There are no other viable alternatives that would achieve the policy objectives of the Regulation.

Benefits and costs of implementation

The Regulation does not impose significant costs on the persons or organisations to which they apply.

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 HIV Foundation Queensland was consulted on the amendments to the Health Regulation and are supportive of the amendments.

Consultation has been undertaken with the Therapeutic Goods Administration, Commonwealth National Industrial Chemicals Notification Scheme, Office of the Health Ombudsman and industry regarding amendments to the Public Health (Infection control for Personal Appearance Services) Regulation. All stakeholders are supportive of the amendments to the Public Health (Infection control for Personal Appearance Services) Regulation.

The Office of Best Practice Regulation, Queensland Productivity Commission, was consulted in relation to the Regulation meeting the requirements of the Regulatory Impact Statement (RIS) System. The Office of Best Practice Regulation advised that a RIS was not required.

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 provides the short title of the Regulation.

Commencement

Clause 2 provides for the commencement of the Regulation. Part 6 of the Regulation commences on 1 January 2016. Part 5 of the Regulation will commence on 1 July 2016.

Part 2 Amendment of Health (Drugs and Poisons) Regulation 1996

Regulation amended

Clause 3 specifies that the Regulation amends the *Health (Drugs and Poisons) Regulation 1996.*

Amendment of s 55 (Carriers)

Clause 4 inserts 'by an authorised person' after 'engaged' in section 55(a) and (b) so that only authorised persons under the Health (Drugs and Poisons) Regulation are prescribed to authorise transport and delivery of a controlled drug. Clause 4 further amends section 55 by defining that an authorised person under this section is a person who is authorised to sell, dispense, supply or issue a controlled drug.

Insertion of new s 78A

Clause 5 inserts new section 78A Approved drug-nabiximols, which reschedules nabiximols from paragraph 3 of Appendix D to paragraph 1 of Appendix D, thus making it available only from, or on the prescription or order of, an authorised specialist health practitioner. Specialist health practitioners include those working in the following specialities:

- the specialty of neurology or rehabilitation medicine, and
- registrars in neurology or rehabilitation medicine working directly under the supervision of specialist health practitioners in the speciality of neurology or rehabilitation medicine.

New section 78A will further allow Sativex™ to be recognised as a therapeutic preparation as a 'regulated controlled drug'.

Amendment of s 82 (Conditions of dispensing)

Clause 6 inserts 'or nabiximols' after 'dronabinol' in section 82(2)(g) to provide that a dispenser must not dispense nabiximols on a prescription that does not state 'approved'.

Amendment of s 158 (Carriers)

Clause 7 inserts 'by an authorised person' after 'engaged' in section 158(a) and (b) so that only authorised persons under the Health (Drugs and Poisons) Regulation are prescribed to authorise transport and delivery of a restricted drug. Clause 7 further amends section 158 by defining that an authorised person under this section is a person who is authorised to sell, dispense, supply or issue a restricted drug.

Amendment of s 271 (Prohibition on dispensing etc. regulated poisons)

Clause 8 amends section 271(1) by replacing the term 'destroy' with the term 'disposes of'. This will provide further disposal options of regulated poisons, such as disposal to approved land fill sites, deep burial in appropriate locations, and incineration at approved facilities.

Insertion of new s 273

Clause 9 inserts new section 273 'Carriers', which allows authorised regulated poison holders to transport and deliver regulated poisons. Clause 9 further defines that an authorised person under this section is a person who is authorised to sell or dispose of the regulated poison.

Amendment of appendix 7 (Regulated poisons)

Clause 10 amends appendix 7, item 7 to prescribe para-amino propriophenone as high risk schedule 7 poison, so that only persons authorised under the Health (Drugs and Poisons) Regulation can use the poison for pest animal control.

Part 3 Amendment of Health Regulation 1996

Regulation amended

Clause 11 specifies that the Regulation amends the *Health Regulation 1996.*

Omission of s 179 (Sale, supply and use of certain therapeutic goods restricted)

Clause 12 omits section 179 which currently restricts the sale, supply and use of a 'reagent', unless the reagent is being sold, supplied and used at an approved hospital or laboratory. Omitting this section will enable the sale, supply and use of a 'reagent' to community-based healthcare settings.

Part 4 Amendment of Mental Health Regulation 2002

Regulation amended

Clause 13 specifies that the Regulation amends the *Mental Health Regulation 2002.*

Amendment of s 5 (Record about seclusion of patients)

Clause 14 amends section 5(1) to correct the numbering reference from 150 to 162L following amendments to the Mental Health Act.

Clause 15 amends the schedule of corresponding laws to include all of the corresponding laws under agreement with another State.

Part 5 Amendment of Public Health (Infection Control for Personal Appearance Services) Regulation 2003

Regulation amended

Clause 16 specifies that the Regulation amends the *Public Health (Infection Control for Personal Appearance Services) Regulation 2003*.

Insertion of new s 5

Clause 17 inserts new section 5 which prescribes tattoo removal as a higher risk personal appearance service under the Public Health (Infection Control for Personal Appearance Services) Act.

Part 6 Amendment of Public Health Regulation 2005

Regulation amended

Clause 18 specifies that the Regulation amends the *Public Health Regulation 2005.*

Amendment of sch 1 (Notifiable conditions)

Clause 19 amends schedule 1 'Notifiable conditions', to ensure that all condition names and case definitions are consistent with contemporary terminology.

Amendment of sch 2 (Immediate notifications)

Clause 20 amends schedule 2 'Immediate notifications', to ensure that all condition names and case definitions are consistent with contemporary terminology.

Amendment of sch 2A (Contagious conditions)

Clause 21 amends schedule 2A 'Contagious conditions', to ensure that all condition names and case definitions are consistent with contemporary terminology.

Part 7 Amendment of Tobacco and Other Smoking Products Regulation 2010

Regulation amended

Clause 22 specifies that the Regulation amends the *Tobacco and Other Smoking Products Regulation 2010.*

Amendment of sch 2 (Prescribed outdoor pedestrian malls)

Clause 23 amends schedule 2 by removing all references to prescribed outdoor pedestrian malls located in Cairns and Townsville.