# Health Legislation Amendment Bill 2014

# Explanatory Notes

## Short title

The short title of the Bill is the Health Legislation Amendment Bill 2014 (the Bill).

## Policy objectives and the reasons for them

The Bill amends eight Health portfolio Acts to support policy initiatives of the Government, and to improve the effective operation of the Acts. In particular, the Bill amends the:

- *Ambulance Service Act 1991* and the *Hospital and Health Boards Act 2011* to make recommended amendments to the legislative framework for Root Cause Analysis (RCA) arising out of the *Review of Root Cause Analysis Legislation*;
- *Health Ombudsman Act 2013* to correct a reference to the Act under which the Privacy Commissioner is appointed;
- *Hospital and Health Boards Act 2011* to include a new exception to the duty of confidentiality to allow the sharing of patient information with non-government service providers who provide public health services for Queensland Health;
- *Mental Health Act 2000* to amend the definition of 'psychiatrist', following changes made to the categories of registration by the Australian Health Practitioner Regulation Agency (AHPRA);
- *Public Health Act 2005* to transfer civil liability for asbestos-related matters from local governments to the State;
- *Radiation Safety Act 1999* to allow the renewal of recently expired renewable Act instruments, to clarify the operation of the Act in relation to banned radiation sources and banned radiation practices, and to clarify the responsibilities for records of the former Radiological Advisory Council of Queensland;
- *Tobacco and Other Smoking Products Act 1998* to give effect to legislative reforms to extend smoking bans on and around health facilities, school grounds, and in prisons; and to apply existing tobacco laws to personal vaporising devices, including prohibiting sale and supply to children, restricting advertising and display at retail outlets, and prohibiting use in smoke-free places; and
- *Transplantation and Anatomy Act 1979* to facilitate national blood supply arrangements, to facilitate legitimate trade in tissue-based therapeutic products, to allow the Minister to delegate functions under the Act, and to clarify that section 17 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* prevails to the extent of any inconsistency.

***Ambulance Service Act 1991* and *Hospital and Health Boards Act 2011* (RCA)**

In 2008, legislation was introduced to provide a statutory framework for the conduct of Root Cause Analysis (RCA) to help improve safety in public and private health services and the Queensland Ambulance Service.

RCA is an internationally recognised approach to the analysis of serious clinical incidents associated with the provision of healthcare, such as those resulting in unexpected death or serious injury. It involves the use of a multidisciplinary team to retrospectively analyse the sequence of events leading to a clinical incident, identify any contributory factors, and make recommendations about how similar events may be prevented from occurring in the future. As an RCA is a resource intensive technique, it is usually only performed on high risk or high impact events.

The conduct of RCAs by public and private health service entities is enabled through the *Hospital and Health Boards Act 2011* and the *Ambulance Service Act 1991*. This legislation facilitates the use of RCA as a quality improvement technique to assess and respond to reportable events that happen while health services are being provided. Consequently, the legislation does not mandate that RCAs be conducted by a particular health service provider, or impose any obligation on those individuals who may have knowledge about a particular incident to participate in the process. Rather, the legislation provides a regulatory framework that provides for the establishment of a multidisciplinary team to retrospectively analyse the chain of events responsible for specified adverse events. The work of the team is focussed on analysing systems (not the performance of individuals) to help find out what happened, why it happened, and what must be done to prevent the event from happening again.

Given that the information obtained through the conduct of an RCA may be of a confidential and/or sensitive nature, the legislation clearly sets out the circumstances under which the information obtained through the conduct of an RCA can be used or disclosed. For example, the legislation:

- imposes a strict duty of confidentiality on RCA team members which prohibits them from making a record, or divulging or communicating information acquired by that person as a member of the RCA team, other than for purposes associated with the conduct of an RCA;
- enables the commissioning authority for an RCA to disclose information to a person with a sufficient personal or professional interest in a reportable event to be given or advised about the RCA team's findings; and
- prevents information obtained during the course of an RCA from being tendered as evidence in court proceedings, or a member of an RCA team being called as a witness due to their involvement in the conduct of an RCA.

Both the *Hospital and Health Boards Act 2011* and *Ambulance Service Act 1991* require a review of the RCA provisions be undertaken to ensure they continue to adequately meet community expectations and that the provisions remain appropriate. Accordingly, a review of the RCA provisions commenced in March 2010, and was led by Queensland Health in consultation with the Queensland Ambulance Service.

The Minister for Health tabled a report on the outcomes of the review, *Review of Root Cause Analysis Legislation*, in the Queensland Parliament on 22 November 2013. The Report recommended a range of amendments to clarify the intent, and improve the workability of, the legislation. These amendments included:

- that 'chain of events' documentation should be treated as part of the RCA report and, as a consequence, subject to the same disclosure and release provisions as an RCA report;
- the decision of an RCA team member to report 'public risk notifiable conduct' to the Australian Health Practitioner Regulation Agency (AHPRA) should be an explicit ground for stopping an RCA;
- RCA teams should be required to notify the commissioning authority of the grounds for stopping an RCA, and the information that forms the basis for that ground; and
- that the application of the RCA provisions should be expanded to include non-government organisations, prescribed under regulation.

Amendments to the *Hospital and Health Boards Act 2011* and *Ambulance Service Act 1991* are required to give effect to these recommendations.

***Health Ombudsman Act 2013***

In order to ensure the transparency and accountability of the health complaints system, the *Health Ombudsman Act 2013* provides that the Health Ombudsman must consult and cooperate with public entities with functions that are relevant to, or may impact on, the Health Ombudsman's functions. For example, the Act requires the Health Ombudsman to consult and cooperate with the Information Commissioner, the Right to Information Commissioner, and the Privacy Commissioner, appointed under the *Right to Information Act 2009*.

While the Information Commissioner and the Right to Information Commissioner are appointed under the *Right to Information Act 2009*, the Privacy Commissioner is appointed under the *Information Privacy Act 2009*. An amendment is required to correct this anomaly.

***Hospital and Health Boards Act 2011***

The *Hospital and Health Boards Act 2011* contains a duty of confidentiality on Queensland Health staff to not disclose patient identifying information to another party, unless authorised to do so under an exception. Breaches of this duty carry a penalty of up to $11,000.

Some Hospital and Health Services (HHSs) contract external service providers to deliver health services, often at Queensland Health facilities, under service level agreements. In Cape York, for example, chronic disease care and maternal and child health services are delivered by the Cape York HHS in partnership with the Royal Flying Doctor Service and Apunipima Cape York Health Council. Under these arrangements, staff of external service providers need to access Queensland Health information systems in order for clinicians and administrative staff to read, review and add information to patient medical records, to ensure continuity of care.

The disclosure of patient information under these agreements is not captured by the existing exceptions to the duty of confidentiality in the *Hospital and Health Boards Act 2011*. Therefore, Queensland Health staff may breach the duty of confidentiality by allowing access to, and entering information into, an information system that staff of external service providers can access. In order to address this issue, amendments are required to prescribe a new exception to the duty of confidentiality to enable staff of external service providers, who are contracted to provide health services for Queensland Health under a service level agreement, to access Queensland Health information systems.

***Mental Health Act 2000***

The *Mental Health Act 2000* provides for the appointment of an 'authorised doctor' to undertake a range of statutory powers and functions. A psychiatrist who is appointed as an authorised doctor is an 'authorised psychiatrist' under the *Mental Health Act 2000*. The powers and functions of an authorised psychiatrist are more extensive than those of an authorised doctor.

A 'psychiatrist' is defined in the *Mental Health Act 2000* as:

- a person registered under the Health Practitioner Regulation National Law (the National Law) to practise in the medical profession as a specialist registrant in the specialty of psychiatry other than as a student; or
- a person registered under the National Law with limited registration to practise in an area of need in a specialist position in psychiatry.

In 2010, the *Health Legislation (Health Practitioner Regulation National Law) Amendment Act 2010* (the Amendment Act) amended the definition of 'psychiatrist' to refer to a person registered under the National Law, rather than the *Medical Practitioners Registration Act 2001* (which was repealed by the Amendment Act). An unintended practical effect of this amendment impacts upon the ability to utilise suitably qualified 'area of need' registrants in remote and regional areas of the State.

An 'area of need' is a geographic or health care service area where there are insufficient medical practitioners with general or specialist registration to provide medical services at a level required by the community. Under the National Law, a person may be granted 'limited registration' in an area of need if that person does not have the full qualifications and accreditation needed for general or specialist registration, but does meet a minimum standard for an area of need as determined by the relevant health practitioner registration board.

Prior to the amendments made to the definition of 'psychiatrist' by the Amendment Act, both specialist registrants (in psychiatry) and limited registrants (that is, area of need registrants practising in a specialist position in psychiatry) were able to perform the function of an authorised psychiatrist under the *Mental Health Act 2000*. However, the amendments in 2010 inadvertently limited this to only specialist registrants.

The *Mental Health Act 2000* was consequently amended again in 2012 to amend the definition of 'psychiatrist', to capture both specialist medical registrants (in psychiatry) and area of need medical registrants (in a specialist psychiatry position) to enable both types of registrants to perform the functions of an 'authorised psychiatrist' under the *Mental Health Act 2000*.

Subsequent to this amendment, the AHPRA introduced a new category of limited registration for postgraduate training or supervised practise. The existing definition of 'psychiatrist' in the *Mental Health Act 2000* does not capture this new category of registration. Failure to take account of the new category of limited registration may have considerable workforce and service delivery implications, as medical practitioners with this type of registration cannot undertake the functions of an authorised psychiatrist under the *Mental Health Act 2000*. Therefore, an amendment to the definition of 'psychiatrist' is required.

***Public Health Act 2005***

Asbestos refers to a set of naturally occurring silicate materials, mined and manufactured into a range of asbestos containing materials. Materials containing asbestos were used extensively in residential and industrial buildings between the 1940s and late 1980s, and were favoured in the construction industry for their physical properties (sound absorption, strength, relative resistance to fire, heat, electrical and chemical damage), and affordability.

Asbestos can still be found in walls, ceilings and roof sheeting, vinyl floor backing, pipes and guttering in domestic premises in Queensland. In a non-workplace setting, exposure to asbestos may potentially occur as a result of maintenance and home renovations, or the demolition of residential homes or other structures where materials containing asbestos were installed before 1990.

Asbestos is a known carcinogen and can present a risk to health when respirable fibres become airborne and are inhaled into the lungs. The risk of disease increases in proportion to the number of fibres breathed in over a lifetime. Asbestos-related disease can take many years to develop. Possible health effects of exposure to asbestos include asbestosis, lung cancer, mesothelioma and benign pleural disease. However, there are safe ways of working on and removing materials containing asbestos that do not present a risk to health of the individual doing the work.

The *Public Health Act 2005* and *Public Health Regulation 2005* include a number of specific measures to control public health risks arising from the release of asbestos fibres as a result of activities carried out in non-workplace settings.

Under the *Public Health Act 2005*, local governments have responsibility for the administration and enforcement of a range of public health risks related to asbestos. These asbestos-related matters may include:

- the dispersal or release of a by-product of manufacturing, construction, repair, alteration, cleaning or demolition work in a non-workplace setting; or
- an accumulation or deposit of a substance or thing associated with asbestos.

The *Public Health Regulation 2005* also sets out a range of measures designed to prevent and control the public health risks associated with the dispersal or release of asbestos fibres in non-workplace settings. These provisions aim to ensure the production of airborne asbestos fibres from activities involving the cleaning, cutting, maintaining removing, storing etc. of materials containing asbestos is reduced or eliminated.

The *Public Health Act 2005* authorises persons appointed by the chief executive (for the State) or a chief executive officer (for local government) to undertake a range of enforcement actions. Authorised persons can use a range of enforcement measures to manage public health risks, including the giving of public health orders, and checking compliance with those orders. Only those persons who are appropriately qualified and have the necessary knowledge, skills and expertise can be appointed as authorised persons.

On 21 March 2013, *The Asbestos Report: An investigation into the regulation of asbestos in Queensland* (the Asbestos Report), prepared by the Queensland Ombudsman was tabled in the Queensland Parliament. It detailed significant gaps and shortcomings in the regulation of asbestos in Queensland, including a lack of coordination and strategic planning by state agencies and councils responsible for responding to asbestos events and issues.

The Asbestos Report made 36 recommendations, which were accepted by the Queensland Government. Recommendation 15 of the Report proposed that the Department of Health work with local governments to resolve whether asbestos should remain a local government public health risk, as defined by the *Public Health Act 2005* and take steps to implement the agreed approach.

As part of the response to the Asbestos Report, the Queensland Government launched the *Statewide Strategic Plan for the Safe Management of Asbestos in Queensland 2014-2019*. The plan targets three priority areas: minimising risk of exposure, coordinated government service delivery, and community education. In developing this plan, the Queensland Government acknowledged the local government's continuing role within the framework of agencies' responsibilities for asbestos-related matters and sought to implement a more collaborative and integrated approach for managing and responding to asbestos-related risks in Queensland.

The Bill gives effect to this intent by addressing the protection from civil liability risks for asbestos-related matters – a key barrier that has prevented local government from being able to fully assume responsibility for the administration and enforcement of asbestos-related matters. This is achieved by transferring civil liability for asbestos-related matters from local governments to the State, conditional upon the local government's sound practices in preventing and managing asbestos-related events, such as Acts, laws and guidelines, staff training, record-keeping and cooperation with the State in the defence of claims. The proposal to transfer civil liability from the local government to the State is a one-off measure.

***Radiation Safety Act 1999***

- **Renewal of expired Act instruments**

The *Radiation Safety Act 1999* provides that a person must not possess, use, transport, acquire or dispose of a radiation source unless they hold an appropriate Act instrument. An Act instrument is defined in the Act as a licence, an accreditation certificate, an approval or a radiation officer certificate. Applications for Act instruments must be made to the chief executive in the approved form, and be accompanied by the fees and documents prescribed under a regulation. The holder of a renewable Act instrument may apply to the chief executive for the renewal of the instrument within 60 days of the instrument's expiry. The application for renewal must be in the approved form and be accompanied by any prescribed fees and any other prescribed documents.

Renewal applications cannot be accepted by the Department of Health if they are received after the Act instruments' expiry dates, and applications are returned to the applicants. In such circumstances, the former holder of an Act instrument must subsequently complete a fresh application and incur the application costs and the associated processing times of a new applicant. This requirement fails to have regard for extenuating circumstances that may prevent a renewal application from being received within the necessary timeframes, for example, an unforeseen medical condition or a delay in postal delivery.

The current framework is imposes a regulatory and financial burden on stakeholders and an administrative burden on government. Amendments are required to allow the renewal of an expired Act instrument to proceed in these extenuating circumstances.

- **Banned radiation sources**

The *Radiation Safety Act 1999* prohibits a person from possessing a radiation source unless the person is authorised under a possession licence. The *Radiation Safety Act 1999* also prohibits a person from acquiring a radiation source unless the person is a possession licensee for the source and has an approval to acquire the source.

The Act goes on to prohibit a person from possessing, supplying or using a radiation source that is prescribed under a regulation to be a banned radiation source. When the *Radiation Safety Act 1999* was first developed, it was envisaged this section would be used to ban radiation sources where there were no other effective measures to prevent or minimise the adverse health risks associated with exposure to these sources.

It has recently been identified that some individuals may try to circumvent the prohibition on banned radiation sources by applying for a possession licence and/or an approval to acquire a banned radiation source. In such circumstances, a decision not to grant a licence would be made by the chief executive which, in turn, could result in appeals. An amendment to the *Radiation Safety Act 1999* is required to clarify that a person cannot apply for a possession licence or an approval to acquire a banned radiation source. Similarly, the chief executive cannot issue an Act instrument for a banned radiation source.

- **Banned radiation practices**

Section 47A of the *Radiation Safety Act 1999* provides that a person in possession of a prescribed radiation source must not allow a radiation practice to be carried out that exposes another person prescribed under a regulation to radiation emitted from the source in the circumstances prescribed under a regulation. At present, this prohibits commercial operators of solaria from allowing minors, or persons with a certain skin type, to access a solarium.

At the time the requirements regarding the banning of certain radiation practices were included in the *Radiation Safety Act 1999*, it was necessary to clarify that although solaria were going to be allow to continue to be used, there were certain practices for which the use of the solaria were far too dangerous to allow. This raised the need for the ability to ban certain practices with radiation sources that were otherwise allowed to be used. When this provision comes into force, the direct link with solaria will be lost because commercial solaria will have been completely banned by that time. However, the ability to ban certain practices using otherwise safe radiation sources will remain. Consequently, amendments are required to retain the ability to ban certain practices using radiation sources.

- **Transitional arrangements**

The *Radioactive Substances Act 1958* was repealed on the commencement of the *Radiation Safety Act 1999*. The Radiological Advisory Council of Queensland was established under the *Radioactive Substances Act 1958*. This Council created, and was responsible for, a number of documents, such as minutes of Council meetings, and various agenda papers.

When the *Radiation Safety Act 1999* was developed, the Radiation Advisory Council was established in lieu of the Radiological Advisory Council of Queensland. However, in a drafting oversight, transitional arrangements were not included in the Act in relation to the documents for which the former council was responsible. There is concern that there is a lack of clarity regarding the Radiation Advisory Council's ability to hold and access records of the former Radiological Advisory Council of Queensland. Because the Radiological Advisory Council and the Radiation Advisory Council have similar functions, ownership of these documents should transfer to the Radiation Advisory Council.

***Tobacco and Other Smoking Products Act 1998***

- **Electronic cigarettes and other personal vaporising devices**

Personal vaporising devices are designed as an alternative to tobacco smoking. Also known as electronic cigarettes, 'vape pens', 'e-shisha' or alternative/electronic nicotine delivery systems, personal vaporising devices mimic the look, feel and function of tobacco cigarettes, and are intended to simulate smoking. The devices heat a fluid, which usually contains liquid nicotine, into a fine vapour for inhalation into the lungs. They do not contain tobacco leaf, require combustion, or produce cigarette smoke.

There are a range of personal vaporising devices on the market, which vary widely in design and operation. However, each device typically consists of a battery, an electronic heating element, and a cartridge or refillable 'tank' containing chemicals such as propylene glycol, vegetable glycerine, liquid nicotine, and flavourings. Users of these devices experience the same deep inhalation of substances into the lungs as cigarettes.

Because these devices do not contain tobacco leaf, they are not automatically covered by tobacco laws, and there are no restrictions relating to their sale and supply, promotion, use or enforcement. Their unregulated availability to children, retail advertising and display, and use in smoke-free public places risks a return to smoking becoming popular and desirable, especially to youth. Years of campaigning by governments and communities to 'de-normalise' smoking and reduce smoking rates could be undermined by the sale and use of electronic cigarettes and other personal vaporisers.

Restrictions relating to personal vaporisers are currently limited to the prohibition of liquid nicotine under the *Health (Drugs and Poisons) Regulation 1996*. Similarly, while the *Tobacco and Other Smoking Products Act 1998* includes a prohibition on the sale of objects that resemble tobacco products, which could be applied to personal vaporisers, it does not adequately cover all product types or address issues about the use of personal vaporisers in public places.

Amendments to the *Tobacco and Other Smoking Products Act 1998* are required to ensure personal vaporising devices and their associated components are subject to the same restrictions applied to tobacco products. This includes prohibiting their sale and supply to children, restricting advertising and display at retail outlets and prohibiting use in enclosed and outdoor smoke-free places.

Applying existing *Tobacco and Other Smoking Product Act 1998* provisions to personal vaporising devices is in line with community expectations for the protection from products that produce smoke and vapour in the manner of smoking. The World Health Organisation and health researchers remain concerned about the inhalation of chemical combinations used across the variety of devices. The scientific evidence regarding short- and long-term health effects of direct or indirect (second-hand) inhalation of vapour from personal vaporising devices remains inconclusive.

- **Prohibition of smoking on and around health facilities and schools**

Currently, the *Tobacco and Other Smoking Products Act 1998* prohibits smoking in all enclosed areas of health facilities and schools. The *Hospital and Health Boards Act 2011* prohibits smoking on public health service land (including a hospital, community health centre, health clinic or rehabilitation centre), but provides discretion for the establishment of a nominated outdoor smoking place on the grounds. Smoking in outdoor areas of state and non-state schools is regulated by policy, and while these policies are well accepted by school communities, there is currently no consistent statewide approach, and smoking bans vary between schools.

Smokers often congregate in groups at points of entry to both health facilities and schools. At schools in particular, parents habitually wait outside school gates to collect their children, often with younger children or babies. The presence of smokers at these points requires visitors, staff and children to move through and be exposed to environmental tobacco smoke. Children's health is particularly affected by exposure to tobacco smoke, with exposure increasing the risk of ear infections or asthma.

To address the public health risks associated with exposure to environmental tobacco smoke at schools and hospitals, it is intended to prohibit smoking on state and non-state school land, as well as on private health facility (including private hospitals or day hospitals) and public health facility land. To ensure smokers extinguish their cigarettes well in advance of entering school or health facility land, amendments are also required to extend the prohibition on smoking to within five metres of the perimeter of these facilities.

- **Prohibition of smoking at secure correctional facilities**

The *Tobacco and Other Smoking Products Act 1998* prohibits smoking in enclosed places, other than private residences, multi-unit residential accommodation, premium gaming rooms and secure correctional facilities as defined by the *Corrective Services Act 2006*.

A prohibition on smoking at all public and private correctional facilities in Queensland took effect from 5 May 2014, following amendments to the *Corrective Services Regulation 2006* to prescribe smoking products and smokeless tobacco products as prohibited things.
Amendments are required to remove the exemption from smoking in secure correctional facilities from the *Tobacco and Other Smoking Products Act 1998*, to ensure consistency with the smoking bans implemented under the *Corrective Services Regulation 2006*.

***Transplantation and Anatomy Act 1979***

- **Buying and selling tissue under national blood arrangements**

Blood and blood products (other than cord blood)

National arrangements for the supply of blood and blood products (other than cord blood – see below) are governed by the *National Blood Agreement*, signed by Australian Health Ministers in 2003. Those arrangements include establishing and jointly funding the National Blood Authority, an administrative unit of the Commonwealth under the *National Blood Authority Act 2003* (Cwth), to manage contracts for collection, production and distribution of blood and limited blood products. These products are listed on the National Product Price List, with corresponding prices, as approved annually by the Council of Australian Government's Health Council (CHC) under the *National Blood Agreement*.

Under these arrangements, companies contracted by the National Blood Authority risk breaching the general prohibitions on trading in tissue in *Transplantation and Anatomy Act 1979* when supplying blood products to the National Blood Authority (for distribution to Queensland), or to Queensland health service providers directly. The Commonwealth (through the National Blood Authority) also risks breaching the *Transplantation and Anatomy Act 1979* by buying the blood products.

While it is possible to partially mitigate this legal risk by prescribing the companies to which the National Blood Authority contracts as 'tissue banks', this course is impracticable. The *Transplantation and Anatomy Act 1979* would limit the prices they could set to 'amounts to recover…reasonable costs associated with removing, evaluating, processing, storing and distributing donated tissue'. If this amount is lower than the National Product List price, the *Transplantation and Anatomy Act 1979* would inhibit effective implementation of the *National Blood Agreement*. It is also possible for the Minister to permit trade of blood products under the *Transplantation and Anatomy Act 1979*. However, this is also impractical and inefficient due to the potentially large number of buyers requiring a permit and the difficulties in satisfying the 'special circumstances' test in required for a permit to be issued.

Amendments to the *Transplantation and Anatomy Act 1979* are required to facilitate the efficient supply of blood and blood-products under national blood supply arrangements.

Cord Blood

Cord blood is blood collected from the placenta following childbirth. It is used for treatment of a range of conditions in children and adults, including leukaemia, lymphoma and anaemia, as well as immune and metabolic disorders. Cord blood transplantation can be used to rebuild the immune system function following high-dose chemotherapy and is increasingly being used as an alternative to bone marrow transplantation.

The donation of public cord blood in Australia is operated by the National Cord Blood Collection Network, under the auspices of the Australian Bone Marrow Donor Registry (ABMDR). The ABMDR is funded by the Commonwealth under a three year funding agreement. While Queensland is not party to this agreement, the States and Territories contribute funding based on the Australian Health Ministers' Advisory Council (AHMAC) cost-shared formula.

Under the agreement, the ABMDR conducts a search for cord blood units used for transplantation required by Queensland patients, and the Commonwealth Government pays for the costs associated with procuring the cord blood unit from international donors. Under separate arrangements, the Commonwealth may also directly pay overseas tissue registries for cord blood on behalf of the ABMDR.

Under these arrangements, the ABMDR risks breaching the *Transplantation and Anatomy Act 1979* prohibitions on trading in tissue. The Commonwealth also risks breaching the prohibitions on the grounds that it is buying tissue with a sufficient connection to Queensland.

Furthermore, if a cord blood unit is collected by the cord blood bank in Queensland (located at the Mater Hospital), and is exported overseas, the receiving country pays for the costs associated with testing, collection, preparation and transport on a cost recovery basis. This funding goes to the Cord Blood Trust Account administered by the ABMDR under agreement with the Commonwealth (with the support of all jurisdictions). The ABMDR risks breaching the *Transplantation and Anatomy act 1979*, as it is cost-recovering for Queensland donated tissue.

It is possible for the Minister to permit trade of cord blood under *Transplantation and Anatomy Act 1979*. However, this is impractical and inefficient due to the potentially large number of buyers requiring a permit and the difficulties in satisfying the 'special circumstances' test required by the Act. In order for the ABMDR to comply with the Act in cost-recovering for donated tissue, it would need to be prescribed as a tissue bank. This is not possible, as it does not fit the definition of a tissue bank.

As with the supply of blood and blood products under national blood supply arrangements, amendments to the *Transplantation and Anatomy Act 1979* are required to facilitate the efficient supply of cord blood.

- **Facilitation of legitimate trade in tissue-based therapeutic products**

The *Transplantation and Anatomy Act 1979* prohibits buying tissue, advertising to buy tissue, and selling tissue (including holding out to sell). The Minister can, if satisfied it is warranted by special circumstances, permit a person to buy tissue. A person who sells to a buyer acting under a ministerial permit is excluded from the selling offence. Public advertising of the right to buy is prohibited unless the advertisement is approved by the Minister.

While the *Transplantation and Anatomy Act 1979* provisions described above are effective in inhibiting commercial trade in human organs and tissue, they are inefficient and counter-productive when applied to tissue products intended for therapeutic or scientific use (which must be approved by the Commonwealth Therapeutic Goods Administration (TGA) for supply in Australia).

Buying and selling is authorised only if conducted pursuant to a ministerial permit, which can only be granted to the buyer in 'special circumstances'. The seller cannot apply for a permit, but must rely on the buyer's permit. However, the seller cannot advertise products or hold out as being willing to sell products, and is therefore prevented from meaningful communication with the buyer. Strictly enforced, these provisions would inhibit timely provision of tissue-based medical products to Queensland patients.

Under the *Therapeutic Goods Act 1989*, a therapeutic good can be supplied in Australia if it is included on the Australian Register of Therapeutic Goods (ARTG). The ARTG has four parts – a part for *biologicals* and a part for *medical devices*, a part for *registered goods*, and a part for *listed goods*. The Bill intends to capture tissue-based therapeutic goods that are included in the ARTG as *registered goods*, *biologicals* or *medical devices*, but not *listed goods*. This is to ensure that tissue-based goods which have not been evaluated by the TGA for safety, quality and efficacy are not exempted from the trading restrictions in the *Transplantation and Anatomy Act 1979*.

- **Delegation of ministerial functions**

Despite having express functions under the *Transplantation and Anatomy Act 1979*, the Minister does not have the power to delegate those functions. The Minister must therefore exercise those functions personally, regardless of the relative importance, risk or impact of any particular matter.

The Minister's specific functions under the *Transplantation and Anatomy Act 1979* are to authorise the buying of human tissue (in 'special circumstances' only), and approve advertisements relating to the buying of tissue. The Act also provides that a proceeding for an offence against part 7 (Prohibition of trading in tissue) shall not be taken without the Minister's written consent.

Amendments to the *Transplantation and Anatomy Act 1979* are required to allow the Minister to delegate the Minister's powers and functions under the Act to an appropriate official, for example, the Director-General of the Department of Health, or the Chief Health Officer.

- **Clarifying primacy of section 17 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003***

The *Transplantation and Anatomy Act 1979*, and section 17 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (the RIHE Act) both prohibit commercial trade in human eggs, sperm or human embryos.

However, the two Acts potentially conflict in relation to reimbursement of reasonable expenses incurred by a person in connection with supply of eggs, sperm or embryos. Such reimbursement is exempted from the prohibition on trading in the RIHE Act, but remains prohibited by general prohibitions against trading in tissue under the *Transplantation and Anatomy Act 1979*.

The RIHE Act is administered by the Department of Health, and applied by assisted reproductive technology providers, on the basis that the specific RIHE Act provision prevails over the general *Transplantation and Anatomy Act 1979* provisions, to the extent of any inconsistency.

An amendment is required to clarify that if the *Transplantation and Anatomy Act 1979* is inconsistent with section 17 of the RIHE Act, the RIHE Act prevails to the extent of the inconsistency. This amendment would provide clarity only, and does not constitute a change of policy or practice.

## Achievement of policy objectives

***Health Ombudsman Act 2013***

The Bill amends the *Health Ombudsman Act 2013* to clarify that the Privacy Commissioner is appointed under the *Information Privacy Act 2009*, and not the *Right to Information Act 2009*.

**Root Cause Analysis**

To give effect to the recommendations of the *Review of Root Cause Analysis Legislation* (the Review), the Bill makes the following amendments to the *Hospital and Health Boards Act 2011* and the *Ambulance Service Act 1991*:

- 'chain of events' documentation is to be treated as part of the RCA report and subject to the same disclosure and release provisions as other RCA documentation. The 'chain of events' documentation will remain inadmissible in legal and disciplinary proceedings;
- a decision by an RCA team member to report 'public risk notifiable conduct' to the AHPRA is an explicit ground for stopping an RCA;
- RCA teams are required to notify the commissioning authority of the grounds for stopping an RCA and the information that forms the basis for that ground; and
- the scope of the legislation is expanded to include non-government organisations prescribed under a regulation.

***Hospital and Health Boards Act 2011***

The Bill amends the *Hospital and Health Boards Act 2011* prescribe a new exception to the duty of confidentiality. This new exception will ensure Queensland Health staff do not breach the duty of confidentiality in circumstances where staff of organisations access Queensland Health information systems while providing health services for the Queensland public health system under funding, service or partnership arrangements.

The new exception incorporates a number of safeguards to help protect the privacy of individuals who are receiving or have received a public sector health service. These safeguards include:

- requiring an agreement between the department of HHS and the external service provider;
- the chief executive authorising access to an information system by an external service provider, or a person engaged by the external service provider; and
- ensuring the external service provider is bound by National Privacy Principles under the *Information Privacy Act 2009*.

***Mental Health Act 2000***

The Bill amends the definition of 'psychiatrist' in the Mental Health Act to include a medical practitioner with limited registration for postgraduate training or supervised practise in a specialist position in psychiatry.

***Public Health Act 2005***

The Bill amends the *Public Health Act 2005* to provide protection from civil liability to local governments for asbestos-related matters for the management of asbestos-related public health risks in non-workplace settings. The protection is offered on a conditional basis to specified local government officers who are acting in an official capacity under the *Public Health Act 2005*, or those persons acting on the direction of that person.

It is important to note that this assumption of liability by the State on behalf of local governments is intended as a 'one off' measure, and should not be seen as an indication of the way the State will address such questions of risk in other areas of local government activity.

***Radiation Safety Act 1999***

- **Renewal of expired Act instruments**

The Bill amends the *Radiation Safety Act 1999* to allow recently expired Act instruments to be renewed. The Bill limits the period within which expired Act instruments can be renewed to applications received within 30 days after the expiry of the instrument.

The decision to renew or refuse to renew an Act instrument is a discretionary power that rests with the chief executive. If an application to renew an Act instrument is received within 30 days after the expiry of the instrument, the chief executive also has the discretion to decide whether it is reasonable to accept the late application in the circumstances.

Allowing the renewal of Act instruments up to 30 days after they have expired is considered less burdensome on holders of Act instruments than having to apply for a new Act instrument. Allowing for renewal of recently expired Act instruments is consistent with the approach taken in other jurisdictions, and under other Queensland legislation.

- **Banned radiation sources**

The Bill amends the *Radiation Safety Act 1999* to clarify that a person cannot apply for a possession licence, or an approval to acquire a banned radiation source. Similarly, the chief executive cannot issue an Act instrument for a banned radiation source.

- **Banned radiation practices**

The Bill amends the *Radiation Safety Act 1999* to remove now redundant definitions.

- **Transitional arrangements**

The Bill amends the *Radiation Safety Act 1999* to include a transitional provision, stating that any documents created or owned by the former Radiological Advisory Council of Queensland are now the responsibility of the Radiation Advisory Council. This ensures the Radiation Advisory Council is able to hold and access the records of the former Council.

***Tobacco and Other Smoking Products Act 1998***

The Bill amends the *Tobacco and Other Smoking Products Act 1998* to capture personal vaporisers and associated products such as liquid flavouring, cartridges and mouthpieces as smoking products under the Act. This will enable existing restrictions for smoking products regarding sale and supply, promotion, use and enforcement to apply to these products. The intent is not to prohibit personal vaporisers from sale, or impose restrictions on contents or design (for example, look, nicotine presence, fluid contents or flavourings), but to provide a regulatory approach that treats these devices in the same way as other tobacco and smoking products.

The Bill amends the *Tobacco and Other Smoking Products Act 1998* to:

- prohibit the sale and supply of personal vaporisers and associated products to children;
- require suppliers to take action to help prevent the sale and supply of personal vaporisers and associated products to children, and to ensure their employees do not supply personal vaporisers and associated products to children;
- prohibit the sale or personal vaporisers and associated products from tobacco product vending machines;
- prohibit display, and restrict advertising, of personal vaporisers and associated products at retail outlets;
- prohibit the promotion of personal vaporisers and associated products through competitions, giveaways and by supplying other products that promote them (for example, a T-shirt that promotes the product);
- prohibit the use of personal vaporisers in smoke-free enclosed places, smoke-free motor vehicles and smoke-free outdoor places; and
- provide an exemption for personal vaporisers and associated products from the prohibition from selling products that resemble tobacco products.

***Transplantation and Anatomy Act 1979***

- **Buying and selling tissue under national blood arrangements**

The Bill amends the *Transplantation and Anatomy Act 1979* to facilitate the supply of blood products for the benefit of Queensland patients, by clarifying that third party suppliers contracted by the Commonwealth or Queensland to supply human tissue products are able to buy, advertise and sell those products in Queensland.

The Bill provides that the general prohibitions on buying, advertising and selling in the *Transplantation and Anatomy Act 1979* do not apply to trading of tissue if two conditions are met. The first condition is that the trade in tissue is carried out by either an *exempt entity* or the Commonwealth acting for the benefit of an exempt entity. The second condition is that the tissue is the subject of an agreement between the exempt entity and the Commonwealth or the State.

There are two types of exempt entities. For blood products, an exempt entity is an entity mentioned as a supplier in the national products price list, agreed annually by the Council of Australian Governments' Health Council under the *National Blood Agreement*, and published by the National Blood Authority. For other tissues, an exempt entity is an entity that is a party to an agreement with the Commonwealth or the State for the buying or selling of tissue, and that has been prescribed in regulation.

Exempt entities will include companies contracted by the National Blood Authority to supply blood products under the *National Blood Agreement*. Entities which may be prescribed include the Australian Bone Marrow Donor Registry.

- **Restriction of trade in TGA-approved products**

The Bill amends the *Transplantation and Anatomy Act 1979* to exempt trade in processed tissue products that are included on the Australian Register of Therapeutic Goods as registered goods (but not listed goods), medical devices or biologicals from the general prohibitions in the *Transplantation and Anatomy Act 1979* on buying, selling and advertising of tissue.

The Bill provides that part 7, sections 40 (Unauthorised buying of tissue prohibited), 41 (Advertising relating to buying of tissue restricted), and 42 (Unauthorised selling of tissue prohibited) do not apply to the trading of tissue if –

a) the tissue has been subjected to processing or treatment; and
b) the trading of the tissue is for a medical purpose, therapeutic purpose or scientific purpose;
c) the tissue is included on the Australian Therapeutic Goods Register as registered good, a medical device or a biological; and
d) the tissue is not a *relevant tissue*.

*Relevant tissue* means tissue stored at a prescribed tissue bank under the *Transplantation and Anatomy Act 1979*, or tissue mentioned in the new section 42AB(1).

These amendments will facilitate legitimate trade in therapeutic products derived from human tissue, such as biomaterials used for the surgical fixation, correction and regeneration of bone and skin.

Provisions of corresponding effect are in place in New South Wales, South Australia, Tasmania, Northern Territory and the Australian Capital Territory.

- **Delegation of ministerial functions**

The Bill provides a power for the Minister to delegate the Minister's powers and functions under the Act to an appropriately qualified public service employee or health service employee. The exercise of this power of delegation is subject to the provisions of the *Acts Interpretation Act 1954*.

The delegation power is policy-neutral. Pursuant to section 27A of the *Acts Interpretation Act 1954*, this amendment allows (but does not require) the Minister to delegate all or some of these functions, subject to conditions determined by the Minister. The Minister can also exercise the function personally in any particular case.

- **Clarifying primacy of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003***

The Bill provides that if there is any inconsistency between the *Transplantation and Anatomy Act 1979* and the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003*, section 17 of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* is to prevail, but only to the extent of the inconsistency.

## Alternative ways of achieving policy objectives

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

## Estimated cost for government implementation

The costs to government associated with implementation of the Bill will be minimal, and will be met from within existing budget allocations.

## Consistency with fundamental legislative principles

**Right to privacy**

The new exception to the duty of confidentiality to enable the sharing of patient-identifying information with external service providers, via access to Queensland Health information systems, infringes on an individual's right to privacy by enabling confidential information about a person's care or treatment at a public health service to be incidentally viewed or accessed without consent (e.g. when searching for a patient with a shared name) while providing a health service to another person.

The former Scrutiny of Legislation Committee and the current Parliamentary Committee have referred to Parliament provisions in legislation that impact on the rights of individuals, including their right to privacy. In the case of doctor-patient confidentiality and public health matters generally, the Parliamentary Committees will consider whether an acceptable balance has been struck between the obvious need to protect and promote the health of the public on the one hand, and the rights and liberties of the individual on the other.

Access to patient identifying information by external service providers engaged by Queensland Health is necessary to provide public health services. The new exception will ensure the duty of confidentiality is not breached if an external service provider accesses a Queensland Health information system for the purpose of providing health services under an agreement between the department or HHS and an external service provider.

Safeguards to address privacy implications include a requirement that the chief executive of the department must be satisfied the disclosure of patient information is necessary for the external service provider to provide a health service. This authorisation must be in writing, must describe the information system to which the authorisation relates, and may be give on conditions stated in the authorisations.

In addition, the new exception requires the external service provider to comply with the National Privacy Principles in the *Information Privacy Act 2009*. This is achieved by the exception capturing the external service provider as a 'bound contracted service provider' under chapter 2, part 4 of the *Information Privacy Act 2009*. Service agreements between entities will include clauses aimed to protect the use of and access to patient information.

**Protection from liability**

In response to stakeholder feedback to the review of the RCA provisions under the *Hospital and Health Boards Act 2011*, the Bill amends the *Hospital and Health Boards Act 2011* to enable a broader range of health services to utilise the RCA provisions for the conduct of RCAs. Currently, the use of RCA provisions is limited to public sector health service facilities and private health facilities (collectively referred to as health service facilities). However, other health service facilities may utilise the RCA provisions if the service is prescribed under a regulation to be a health service facility.

As a consequence of this amendment, section 116 of the *Hospital and Health Boards Act 2011* has also been amended. Section 116 provides statutory protections for RCA team members or a relevant person for an RCA team, including protection from liability associated with a civil claim, defamation, breach of confidentiality and disciplinary action. Section 116 goes on to specify that a member of an RCA team or a relevant person for an RCA team must be indemnified, as well as specifying who must provide such indemnity. In the case of an RCA commissioned for a health service provided by a prescribe health service facility, the body responsible for providing indemnity will also be prescribed by regulation. This approach is recommended as the person or entity responsibly for providing indemnity will vary depending on which health service providers seek to become a prescribed health service facility.

The amendment to section 116 may raise the issue of whether the legislation has sufficient regard to the rights and liberties of individuals by conferring immunity from proceedings or prosecution without adequate justification. However, it is considered that the amendment is justified on the following grounds:

- it is not appropriate for an individual to be made personally liable as a consequence of that individual agreeing to carry out the responsibilities of an RCA team member or a relevant person;
- protection from liability is only provided on the basis that when carrying out their statutory functions under the Act, an individual acted honestly and without negligence; and
- the provision does not remove an aggrieved person's right to take action, it merely shift liability from the individual officer to the entity that appointed the RCA team.

While persons are appointed to RCA teams, a person cannot be compelled to become a member of an RCA team. Rather, the voluntary participation of health professionals is sought to form a multidisciplinary team that is then responsible for retrospectively analysing a clinical incident and making recommendations about whether latent weaknesses in healthcare systems and processes can be eliminated or mitigated.

An important factor in gaining cooperation of health professionals in the conduct of RCAs i the statutory protection provided by the legislation, which ensures they can fulfil their responsibilities as an RCA team member without fear that their involvement will result in future repercussions or reprisals. As detailed in the report on the *Review of Root Cause Analysis Legislation*, stakeholders were of the view that the statutory protections provided in the legislation were a positive aspect of the regulatory framework for the conduct of RCAs.

**Asbestos**

The amendments to the *Public Health Act 2005* may raise the issue of whether the legislation has sufficient regard to the rights and liberties of individuals by conferring immunity from proceedings or prosecution without adequate justification. However, the amendments will not deny an aggrieved person the right to take action, as the local government retains civil liability but may be indemnified by the State in particular circumstances. Therefore, the amendment is not considered to offend the fundamental legislative principle about not conferring immunity from proceedings without adequate justification.

**Sub-delegation of power**

The amendments to the *Transplantation and Anatomy Act 1979* allow a regulation to prescribe an entity, which has an agreement with the Commonwealth or State for the buying or selling of tissue, as an exempt entity. The amendments to the *Transplantation and Anatomy Act 1979* excuses an exempt entity from the restrictions in the Act on buying, advertising and selling of tissue if the tissue is the subject of an agreement with the Commonwealth or the State.

The proposed amendments potentially infringe the fundamental legislative principles that an Act should allow the delegation of legislative power only in appropriate cases and to appropriate persons, and that Acts of Parliament should only be amended by another Act. The potential infringement is justified on the basis that prescribing an entity in regulation is necessary to allow third parties to identify which entities are exempt. Due to commercial confidentiality, it would otherwise be difficult for third parties to identify which entities are party to an agreement with the Commonwealth or the State for the buying or selling of tissue. Without this knowledge, the third parties would not be able to manage their legal risk.

**Rights and liberties of individuals**

The introduction of smoking bans at hospitals and schools, and the widening of smoking offences across the *Tobacco and Other Smoking Products Act 1998* to include personal vaporisers, may infringe on the principle that an Act should have sufficient regard to the rights of individuals. The former Scrutiny of Legislation Committee has referred to Parliament the question of whether legislation that prohibits smoking in public or semi-public areas has sufficient regard to the rights of smokers, of persons conducting businesses, and of the community in general.

Environmental tobacco smoke comprises second-hand smoke exhaled by a smoker and ‘sidestream’ smoke from a smouldering cigarette. People exposed to environmental tobacco smoke inhale most of the same toxins that smokers inhale directly through cigarettes, and are also at risk of developing lung cancer, heart disease and respiratory conditions.

Children's health is particularly affected by exposure to tobacco smoke, with exposure increasing risks of ear infections and asthma. Scientific evidence has established that there is no safe level of exposure to environmental tobacco smoke and it is estimated that about 10% of smoking-related deaths are a result of exposure to environmental tobacco smoke.

The congregation of smokers at nominated smoking places or entry points to hospitals, and entry points to schools, exposes the non-smoking community, including children and other vulnerable persons, to environmental tobacco smoke. This exposure is often unavoidable, given the proximity to entry and exit points. There has been strong community support for smoke-free outdoor areas where children or vulnerable persons are at risk of exposure to environmental tobacco smoke.

Smokers are not prohibited from smoking near hospitals and schools, but must do so outside of a five metre buffer (subject to other outdoor smoking laws). It is therefore considered that the amendments strike an appropriate balance between protecting the health of non-smokers and vulnerable persons, and infringing on an individual's right to smoke in a public or semi-public area.

In relation to the removal of the smoking ban exemption at prisons, the amendment to the *Tobacco and Other Smoking Products Act 1998* is consequential. Queensland correctional centres have been smoke-free since May 2014, following amendments to the *Corrective Services Regulation 2006* to capture smoking products as 'prohibited things', thus prohibiting the possession of smoking products at a secure correctional facility. Enforcement is therefore undertaken by dealing with prohibited things under the *Corrective Services Act 2006*.

**Introduction of new offences**

The amendments to the *Tobacco and Other Smoking Products Act 1998* include a number of new offences for smoking on health facility land or school land (including a five metre buffer around the land) and for continuing to smoke after being direct to stop smoking. These new offences may infringe on the principle of whether an Act has sufficient regard to the rights and liberties of individuals by introducing new offences. It is also necessary to ensure that penalties are proportionate to the offence and are consistent with each other.

Smoking is currently prohibited on public health facility grounds (outside of a nominated smoking place, if one has been established), under the *Hospital and Health Boards Act 2011*. The smoking offence has been removed from that Act and transferred to the *Tobacco and Other Smoking Products Act 1998*, and then expanded to private health facility land and a five metre buffer around the land. The introduction of offences for this smoking bans is necessary to ensure compliance and to afford the public protection from environmental tobacco smoke.

The offence to stop smoking when directed is consistent with a similar power for other smoking offences through the *Tobacco and Other Smoking Products Act 1998*, and is necessary for enforcement.

The penalties for these offences are consistent with similar smoking offences under the *Tobacco and Other Smoking Products Act 1998*.

## Consultation

A consultation draft of the amendments to the *Transplantation and Anatomy Act 1979* was provided to:

- Organ and Tissue Donation Service, Metro South HHS
- Queensland Fertility Group
- National Blood Authority
- Australian Bone Marrow Donor Registry
- Johnson and Johnson Medical Pty Ltd
- Baxter Healthcare Pty Ltd and
- Ramsay Health Care.

Consultation on the amendments to the *Tobacco and Other Smoking Products Act 1998*, regarding smoking bans, was undertaken with:

- Local Government Association of Queensland
- Private Hospitals Association of Queensland
- Independent Schools Queensland and
- Queensland Catholic Education Commission

The Local Government Association of Queensland was also consulted regarding the amendments to the *Public Health Act 2005*.

Stakeholder feedback was considered and incorporated, where appropriate, during the development of the Bill.

## Consistency with legislation of other jurisdictions

The Bill is specific to the State of Queensland with the exception of the matters outlined below.

- **Duty of confidentiality**

The legislation governing confidential and/or personal health information differs between jurisdictions. South Australia's *Health Act 2008* includes an exception to the duty of confidentiality if a person discloses information by entering the information into an electronic record system established for the purpose of enabling the recording or sharing of information between persons or bodies involved in the provision of health services.

Similarly, Victoria's *Health Services Act 1988* includes an exception to the duty of confidentiality where the information is given by a person engaged or employed by or on behalf of a public hospital or denominational hospital by means of an electronic records system established for the purpose of enabling the sharing of information in or between public hospitals and denominational hospitals for the treatment of patients at any time.

Federally, the *Privacy Act 1988* is an Act to make provision to protect the privacy of individuals and for related purposes. The Act provides that it is the intention of Parliament that the Act is not to affect the operation of a law of a State or Territory that makes provision with respect to the collection, holding, use, correction, disclosure or transfer of personal information and is capable of operating concurrently with the Act.

- **Tobacco and Other Smoking Products Act**

To date, no other jurisdiction has enacted legislation similar to the amendments regarding personal vaporisers. All States and Territories prohibit liquid nicotine under poisons regulations. South Australia, New South Wales, the Northern Territory and Western Australia have general provisions in their state-based tobacco legislation that prohibit the sale of objects resembling tobacco products. Similar to Queensland, these rules do not adequately cover all product types or address issues about personal vaporiser use in public places.

In relation to the prohibition on smoking on health service land, most other jurisdictions use policy mechanisms in all or defined outdoor areas of hospital grounds. Tasmania is the only jurisdiction that has legislation banning smoking in all enclosed and outdoor areas of departmental land and facilities, including health and hospital facilities. No other jurisdiction has introduced a non-smoking buffer around health facility land.

Similarly, prohibitions on smoking at educational facilities in other jurisdictions are largely policy based. The Northern Territory is the only jurisdiction that has legislation banning smoking on school grounds, however, schools have the option to create an outdoor nominated smoking area. Tasmania is the only jurisdiction to restrict smoking beyond the school perimeter. Tasmania's non-smoking policy includes a specific 'buffer zone' around crossing guards employed by the state when undertaking their duties at crossings.

In relation to the prohibition on smoking in an on prison grounds, the Northern Territory is the only jurisdiction to have successfully banned smoking in prisons.

- **Transplantation and Anatomy Act**

Each jurisdiction has enacted legislation to govern the donation of organ and tissues for transplantation or other therapeutic, medical or scientific purposes, modelled on the Draft Legislation in the Law Reform Commission Report No. 7, Human Tissue Transplants. While the overall legislative framework continues to be consistent, each jurisdiction has modified particular aspects of their legislation since the model legislation was developed.

The amendments in the Bill to facilitate trade in therapeutic products derived from human tissue are broadly consistent with corresponding provisions in New South Wales, South Australia, Tasmania, Northern Territory and the Australian Capital Territory.

- **Radiation Safety Act**

Allowing for the renewal of expired renewable Act instruments up to 30 days after expiry is consistent with approaches taken in other jurisdictions. For example, the Australian Capital Territory, South Australia and the Northern Territory accept applications for renewal up to 30 days after expiry; New South Wales and Victoria up to 60 days after expiry; up to 45 days after expiry in Western Australia, and up to 90 days after expiry in Tasmania.

# Notes on provisions

## Part 1 Preliminary

### Short title

*Clause 1* provides that, when enacted, the short title of the Act will be the *Health Legislation Amendment Act 2014.*

### Commencement

*Clause 2* provides for commencement of the Act.

## Part 2 Amendment of Ambulance Service Act 1991

### Act amended

*Clause 3* specifies that this part amends the *Ambulance Service Act 1991*.

### Amendment of s 36A (Definitions for pt 4A)

*Clause 4* amends section 36A to remove the definition of 'chain of events document' and to remove the reference to 'chain of events document' from the definition of 'relevant person'. These amendments, together with further amendments throughout this Part, give effect to Recommendation 2 of the *Report on the Review of Root Cause Analysis Legislation*, to treat 'chain of events' documentation as part of the RCA report, and therefore subject to the same disclosure and release provisions.

The clause also amends the definition of 'reportable event' to clarify that, in relation to an RCA report, a reportable event means the event to which the report relates.

### Amendment of s 36G (RCA team's report and chain of events document)

*Clause 5* amends section 36G to remove the reference to 'chain of events document' from the section heading and to remove the definition of 'chain of events documents'. Instead, section 36G is amended to state that an RCA report may include a summary of a chain of events, that details or pictorially represents the chain of events identified by the RCA team as having led to the occurrence of a reportable event.

### Amendment of s 36H (Reporting to commissioning authority)

*Clause 6* amends section 36H to remove the requirement in subsection (2) that, if an RCA team prepares a chain of events document for a reportable event, it must give the document to the commissioning authority at the same time as an RCA report.

## Amendment of s 36J (Stopping conduct of RCA of reportable event––RCA team)

*Clause 7* amends section 36J to provide that an RCA team may stop conducting an RCA if a member of the RCA team, who is a registered health practitioner, reports public risk notifiable conduct relating to the reportable event to the health ombudsman. This amendment gives effect to Recommendation 3 of the *Report on the Review of Root Cause Analysis Legislation*, to include a decision of an RCA team member to report 'public risk notifiable conduct' to the health ombudsman as an explicit ground for stopping an RCA.

This clause inserts a new requirement into section 36J, that where an RCA team stops conducting an RCA and gives notice to the commissioning authority the notice must contain information about the reasons for stopping the RCA. This is in addition to the existing requirements that the notice must be in an approved form. This amendment gives effect to Recommendation 4 of the *Report on the Review of Root Cause Analysis Legislation*, to require RCA teams to notify the commissioning authority of the grounds for stopping an RCA and the information that forms the basis for that ground.

Previously, section 36J prevented an RCA team from providing any information to the commissioning authority about why they stopped conducting an RCA. However, this created a situation where the commissioning authority had insufficient information to direct further investigation. This amendment will allow the commissioning authority to make a more informed decision about what further investigations or actions are required, and will increase the transparency and ability to act further when an RCA team has reasonable grounds to decide to stop conducting an RCA.

As a result of the above amendments, the subsections in section 36J are renumbered.

## Amendment of s 36K (stopping of conduct of RCA of reportable event––commissioning authority)

*Clause 8* amends section 36K to provide that, where a commissioning authority receives information, other than in a notice received under section 36J(3)(b), that leads the commissioning authority to reasonably believe the event involves a blameworthy act, or the capacity of a person who was directly involved in providing the relevant ambulance service to safely and effectively provide the service was impaired by alcohol or a drug, the commissioning authority must direct the RCA team to stop conducting the RCA. It is not necessary to capture the notice in section 36J(3)(b) because under that section, an RCA team will have already stopped conducting an RCA. The notice under section 36J(3)(b) notifies the commissioning authority of the grounds for stopping the RCA.

## Amendment of s 36L (Definitions for div 5)

*Clause 9* amends section 36L to remove the definition for 'National Agency'. This is because the reference to National Agency is being replaced with 'health ombudsman', which is defined in the schedule to the Act. The clause also relocates the definitions for the terms 'public risk notifiable conduct' and 'registered health practitioner' to section 36A, to reflect that these terms now apply across the entire of part 4A, and not just to division 5 of part 4A.

### Amendment of s 36M (Disclosure of information––RCA team member or relevant person)

*Clause 10* amends section 36M to remove the reference to 'chain of events' document, and replaces the reference to 'National Agency' with a reference to the 'health ombudsman'. This amendment arises as a result of the establishment of the Health Ombudsman, who took over functions for receiving notifications under the Health Practitioner Regulation National Law.

### Amendment of s 36N (Disclosure of information––commissioning authority or relevant person)

*Clause 11* amends section 36N to remove the references to 'chain of events document'. The clause also inserts a new subsection (7) to provide that a person who is or was a commissioning authority must not disclose to someone else, information contained in a notice given to the person under section 36J(3)(b), or give someone else a copy of the notice.

The amendments also provide that the non-disclosure requirement does not apply to the disclosure of information by a person that is required under section 36Q(7), or necessary or incidental to the person taking, or deciding to take, disciplinary or other action in relation to the reportable event the subject of the information.

### Amendment of S 36P (Giving copy of RCA report or chain of events document-medical director)

*Clause 12* amends section 36P to remove references to 'chain of events document'. The clause also removes references to the phrase 'or document', which is a reference to a chain of events document.

### Amendment of s 36Q (Giving of copy of RCA report etc.-investigation under the Coroners Act 2003)

*Clause 13* amends section 36Q to correct a numbering reference to section 36J. The clause also amends the definition of 'stop notice' to mean a notice stating the fact that the RCA team stopped conducting the RCA under section 36J(3) and the reasons for stopping.

### Insertion of new pt 8, div 7

*Clause 14* inserts a transitional provision to ensure the confidential obligations continue to apply in relation to chain of events documents that were prepared before the amendments.

### Amendment of sch (Dictionary)

*Clause 15* amends the dictionary in the schedule to remove the definitions for 'chain of events document' and 'National Agency'. This clause also amends the definitions for 'public risk notifiable conduct' and 'registered health practitioner' to remove the references to 'division 5' and to replace the reference to section 36L with section 36A, as a result of moving the definitions for these terms in the Act under clause 9.

# Part 3 Amendment of Health Ombudsman Act 2013

## Act amended

*Clause 16* specifies that this part amends the *Health Ombudsman Act 2013*.

## Amendment of s 30 (Cooperation with other entities)

*Clause 17* amends section 30 to correct an error in existing paragraph (f), which refers to the Privacy Commissioner being appointed under the *Right to Information Act 2009*. The amendment clarifies that the Information Commissioner and Right To Information Commissioner are appointed under the *Right to Information Act 2009* and the Privacy Commissioner is appointed under the *Information Privacy Act 2009*. As a result, these two entries are separated into paragraphs (f) and (g), so the clause renumbers the paragraphs in section 30 to account for this.

## Amendment of s 228 (Power to require information)

*Clause 18* amends section 228 to correct an incorrect reference to a subsection.

# Part 4 Amendment of Hospital and Health Boards Act 2011

## Act amended

*Clause 19* specifies that this part amends the *Hospital and Health Boards Act 2011*.

## Amendment of s 46 (Delegation by chief executive)

*Clause 20* amends section 46 to specify that, if the chief executive delegates his or her authority under section 161A to a health service chief executive, the health service chief executive is not permitted to sub-delegate authorisation of access to an information system containing confidential information, by an external service provider. This amendment arises as a result of the insertion of a new exception to the duty of confidentiality, to allow external service providers to access Queensland Health information systems to provide public health services under a service level agreement with the department or an HHS.

This clause also omits subsection (7), as the requirement to ensure delegation is to an appropriately qualified person is now captured under the *Acts Interpretation Act 1954*. As a result of this amendment, the paragraphs are renumbered.

## Amendment of s 84 (Disclosure of information)

*Clause 21* amends section 84 to change a reference to the 'National Agency' to the health ombudsman. The effect of this amendment is that where a member of a quality assurance committee established under section 82 of the *Hospital and Health Boards Act 2011* could previously disclose information to the Australian Health Practitioner Regulation Agency, they are now authorised to disclose that information to the health ombudsman instead.

This amendment arises as a result of the establishment of the Health Ombudsman, who took over functions for receiving notifications under the Health Practitioner Regulation National Law.

### Amendment of s 94 (Definitions for div 2)

*Clause 22* amends section 94 to remove the definition of 'chain of event's document'. As with similar amendments to the *Ambulance Services Act 1991*, this amendment, together with further amendments throughout this part, give effect to Recommendation 2 of the *Report on the Review of Root Cause Analysis Legislation*, to treat 'chain of events' documentation as part of the RCA report, and therefore subject to the same disclosure and release provisions.

The clause also amends the definition of 'health service facility' to include a prescribed health service facility, and inserts a new definition for the term 'prescribed health service facility'. These amendments, together with further amendments regarding prescribed health service facilities throughout this part, give effect to Recommendation 5 of the *Report on the Review of Root Cause Analysis Legislation*, to expand the scope of the RCA legislation to include non-government organisations prescribed under a regulation.

The clause amends the definition of 'reportable event' to clarify that, in relation to an RCA report, means the reportable event to which the report relates.

### Amendment of s 98 (Appointment of RCA team)

*Clause 23* amends section 98 to include a prescribed health service facility. The effect of this amendment is that a commissioning authority can appoint persons at a prescribed health service facility to be members of an RCA team.

### Amendment of s 100 (RCA team's report and chain of events document)

*Clause 24* amends section 100 to remove the reference to 'chain of events document' from the section heading and to remove the definition of 'chain of events documents'. Instead, section 100 is amended to state that an RCA report may include a summary of a chain of events, that details or pictorially represents the chain of events identified by the RCA team as having led to the occurrence of a reportable event.

### Amendment of s 101 (Report to commissioning authority)

*Clause 25* amends section 101 to remove the requirement that, if an RCA team prepares a chain of events document for a reportable event, it must give the document to the commissioning authority at the same time as an RCA report.

### Amendment of s 102 (Stopping conduct of RCA of reportable events––RCA team)

*Clause 26* amends section 102 to provide that an RCA team may stop conducting an RCA if a member of the RCA team, who is a registered health practitioner, reports public risk notifiable conduct relating to the reportable event to the health ombudsman. This amendment gives effect to Recommendation 3 of the *Report on the Review of Root Cause Analysis Legislation*, to include a decision of an RCA team member to report 'public risk notifiable conduct' to the health ombudsman as an explicit ground for stopping an RCA.

This clause inserts a new requirement into section 102, that where an RCA team stops conducting an RCA and gives notice to the commissioning authority, the notice must contain information about the reasons for stopping the RCA. This amendment gives effect to Recommendation 4 of the *Report on the Review of Root Cause Analysis Legislation*, to require RCA teams to notify the Commissioning Authority of the grounds for stopping an RCA and the information that forms the basis for that ground.

Previously, section 102 prevented an RCA team from providing any information to the commissioning authority about why they stopped conducting an RCA. However, this created a situation where the commissioning authority had insufficient information to direct further investigation. This amendment will allow the commissioning authority to make a more informed decision about what further investigations or actions are required, and will increase the transparency and ability to act further when an RCA team has reasonable grounds to decide to stop conducting an RCA.

As a result of the above amendments, the subsections in section 102 are renumbered.

### Amendment of s 103 (Stopping conduct of RCA of reportable events––commissioning authority)

*Clause 27* amends section 103 to provide that, where a commissioning authority receives information, other than in a notice received under section 102(3)(b), that leads the commissioning authority to reasonably believes the event involves a blameworthy act, or the capacity of a person who was directly involved in providing the relevant ambulance service to safely and effectively provide the service was impaired by alcohol or a drug, the commissioning authority must direct the RCA team to stop conducting the RCA. It is not necessary to capture the notice in section 102(3)(b) because under that section, an RCA team will have already stopped conducting an RCA. The notice under section 102(3)(b) notifies the commissioning authority of the grounds for stopping the RCA.

### Amendment of s 105 (Disclosure of information––RCA team member or relevant person)

*Clause 28* amends section 105 to remove the reference to 'chain of events document', and replaces the reference to 'National Agency' with a reference to health ombudsman. This amendment arises as a result of the establishment of the Health Ombudsman, who took over functions for receiving notifications under the Health Practitioner Regulation National Law.

### Amendment of s 106 (Disclosure of information––commissioning authority or relevant person)

*Clause 29* amends section 106 to remove the references to 'chain of events document'. The clause also inserts a new subsection (7) to provide that a person who is or was a commissioning authority must not disclose to someone else information contained in a notice given to the person under section 102(3)(b) or give someone else a copy of the notice.

The amendments also provide that the non-disclosure requirement does not apply to the disclosure of information by a person that is required under section 113(7), or necessary or incidental to the person taking, or deciding to take, disciplinary, investigative or other action in relation to the reportable event the subject of the information.

### Amendment of s 112 (Giving of copy of RCA report or chain of events document––patient safety entity)

*Clause 30* amends section 112 to remove references to 'chain of events document'. The clause also removes references to the phrase 'or document', which a reference to a chain of events document.

### Amendment of s 113 (Giving of copy of RCA report etc.––investigation under the Coroners Act 2003)

*Clause 31* amends section 113 to correct a numbering reference to section 102(3). The clause also amends the definition of 'stop notice' to mean a notice stating that an RCA team stopped conducting the RCA under section 102(3) and the reasons for stopping.

### Amendment of s 116 (Protection from liability)

*Clause 32* amends section 116 to insert a protection from liability to recognise when an RCA has been commissioned for a reportable event at a prescribed health service facility. The amendment provides that, if an individual has the day-to-day management of a prescribed health service facility or the individual who has overall management responsibility for the facility appointed the RCA team members, a regulation will prescribe the person who must provide indemnity. This amendment extends the current protection from liability to reflect expanding the scope of the RCA legislation to include non-government organisations prescribed under a regulation.

### Amendment of s 119 (Protection for documents and information)

*Clause 33* amends section 119 to remove references to 'chain of events document'. Because the chain of events document will now form part of the RCA report, there is no need to prevent the documents from being access under a judicial or administrative order, or prevent it from being admissible in any proceeding.

### Amendment of s 139 (Definitions for pt 7)

*Clause 34* amends section 139 to insert definitions for 'external service provider' and 'information system'. These terms are used to the new exception to the duty of confidentiality in new division 3 of part 7.

### Amendment of s 156 (Disclosure to health ombudsman)

*Clause 35* amends section 156 to provide that, in addition to disclosing confidential information to the health ombudsman for the purposes of making, or giving information about a complaint, a designated person may also disclose confidential information for the purpose of making, or giving information about a complaint under the Health Practitioner Regulation National Law.

### Insertion of new pt 7, div 3

*Clause 36* inserts new division 3 into part 7, to provide a new exception to the duty of confidentiality for external service providers, engaged by Queensland Health under a service level agreement to provide public health services, to access Queensland Health information systems. The new division comprises new sections 161A and 161B.

Section 142 prohibits a designated person from disclosing, directly or indirectly, confidential information to another person, unless the disclosure is required or permitted under the *Hospital and Health Boards Act 2011*. Confidential information is information from which a person who is receiving or has received a public sector health service could be identified. The remainder of part 7, division 2 consists of exceptions to this duty of confidentiality, for example where a designated person may disclose confidential information for the care and treatment of the person to whom the information relates.

Section 143 provides an exception to the duty of confidentiality where disclosure of confidential information by a designated person is required or permitted by an Act or law. It is this section that is relied upon to enable disclosure – by way of access to Queensland Health information systems – under new sections 161A and 161B.

New section 161A provides that the chief executive may authorise an external service provider to access a Queensland Health information system. This system could be electronic, paper-based or both.

Before authorising access, the chief executive must be satisfied the access is necessary to enable the external service provider to provide a health service under an agreement between the chief executive or an HHS and the service provider. Further, the authorisation must be in writing and must describe the information system or systems to which the authorisation relates. This new section provides a safeguard to ensure scrutiny of a proposal to enable an external service provider to access confidential information.

New section 161B provides the authority for an external service provider, or a person engaged by that provider, to access a Queensland Health information system under an authorisation in section 161A.

As a further safeguard, this section states that the external service provider is taken to be a bound contracted service provider under the *Information Privacy Act 2009*, for the purposes of chapter 2, part 4 of that Act. This ensures that the National Privacy Principles in the *Information Privacy Act 2009* apply to the external service provider. This requirement will help to manage risks relating to further disclosure, use, security etc. of the confidential information, as significant penalties apply to non-compliance with the *Information Privacy Act 2009*.

## Omission of s 184 (Prohibition of smoking)

*Clause 37* omits section 184. This clause established that a person must not smoke on health service land, other than in a nominated smoking place. Amendments to the *Tobacco and Other Smoking Products Act 1998* will capture smoking at public health facilities. Therefore, the smoking ban under the *Hospital and Health Boards Act 2011* is made redundant.

## Insertion of new pt 13, div 5

*Clause 38* inserts a transitional provision to ensure the confidential obligations continue to apply in relation to chain of events documents that were prepared before the amendments.

### Amendment of sch 2 (Dictionary)

*Clause 39* amends the dictionary in schedule 2 to remove the definition for 'chain of events document'.

## Part 5 Amendment of Mental Health Act 2000

### Act amended

*Clause 40* specifies that this part amends the *Mental Health Act 2000*.

### Amendment of schedule (Dictionary)

*Clause 41* amends the definition of 'psychiatrist' to include a person registered under the Health Practitioner Regulation National Law with limited registration to undertake postgraduate training or supervised practice in a specialist position in psychiatry. This amendment gives effect to a new category of limited registration

## Part 6 Amendment of Public Health Act 2005

### Act amended

*Clause 42* specifies that this part amends the *Public Health Act 2005*

### Insertion of new ch 11, pt 1A

*Clause 43* inserts a new part 1A into chapter 11. Part 1A consists of three new divisions. Division 1 (Preliminary) comprises new section 454A, division 2 (Protection from civil liability and indemnity) comprises new sections 454B to 454E, and division 3 (Indemnity conditions) comprises new sections 454F to 454L.

Section 454A sets out the definitions for new part 1A, as follows:

- *Annual compliance certificate* means a certificate provided under new section 454J(1).
- *Asbestos-related event* means an event that involves the exposure, release or dispersal, or potential exposure, release or dispersal, of asbestos fibres, and is related to the performance of a local government's asbestos-related functions.
- *Asbestos-related function* means the administration and enforcement of the *Public Health Act 2005* by a local government, for a public health risk mentioned in section 11(1)(b)(v) or (viii) of the *Public Health Act 2005*, to the extent the risk relates to asbestos at a place other than a workplace. A public health risk is defined in section 11(1)(b)(v) as waste (including an accumulation or deposit of a substance) that is or is likely to be hazardous to human health, or that contributes to or is likely to contribute to disease in humans or the transmission of an infectious condition. Section 11(1)(b)(viii) defines a public health risk as a dispersal or release of a by-product of manufacturing, construction, repair, alteration, cleaning or demolition at a place other than a workplace that is, or is likely to be hazardous to human health.

- *Asbestos-related harm* means harm that is, or is suffered because of, a dust-related condition within the meaning of the *Civil Liability Act 2003* that is attributable to asbestos. This will capture, for example, the following diseases: asbestos induced carcinoma, asbestosis, asbestos-related pleural diseases and mesothelioma.
- *Conduct* means an act or omission to act under the *Public Health Act 2005*.
- *Harm* means harm of any kind, other than property damage, including personal injury (which includes disease, psychological or psychiatric injury and fatal injury) and economic loss.
- *Indemnity conditions* means the conditions set out in new section 454F.
- *Official conduct* means the conduct engaged in by a prescribed person as part of, or in connection with, the performance of a local government's asbestos-related function.
- *Prescribed person* means: a chief executive officer of a local government; an authorised person appointed by the chief executive officer of a local government (under section 377(2) of the *Public Health Act 2005*); or a person acting under the direction of a chief executive officer of a local government or an authorised person. The intent of this definition is to describe the persons to whom indemnity is provided (subject to other conditions within part 1A). Third-party contractors are not captured, unless the contractor is appointed as an 'authorised person' under the *Public Health Act 2005*.
- *Third-party contractor* means a person engaged by the local government under a contract to provide services to assist the local government with the performance of its asbestos-related functions. It is not intended that this definition capture a third-party contractor that is appointed as an authorised person by the local government.

Section 454B provides that a prescribed person is not civilly liable for official conduct engaged in by the person, if that conduct gives rise to asbestos-related harm. Currently, section 456 of the *Public Health Act 2005* provides for those persons involved in the administration and enforcement of the Act to be protected from civil liability for an act done, or an omission made, honestly and without negligence under the Act. In these circumstances, liability is transferred to the local government. Section 456 will only indemnify prescribed persons in the absence of negligence, which is of little use for a claim against a prescribed person for an act or omission in relation to an asbestos-related risk if the claim involves negligence. The new provision provides a protection from civil liability where official conduct giving rise to the liability was engaged in other than in good faith and with gross negligence. The new provision seeks to be consistent with contemporary civil liability provisions under the *Public Service Act 2008*.

Section 454C sets out the circumstances under which a local government is indemnified by the State against asbestos-related civil liability. In order to be indemnified by the State, the local government must have reasonably complied with the conditions for indemnity (*indemnity conditions*), which are set out in division 3 of new part 1A. Local governments may provide an annual certification regarding their compliance with these conditions for asbestos-related events under division 4 of new part 1A, which is taken to be evidence of compliance with the conditions. However, in circumstances where compliance with the conditions is disputed, section 454C clarifies that the onus is on the local government to prove that it has reasonably complied with the indemnity conditions. Where a local government is indemnified by the State, the State assumes the rights of the local government in relation to the civil liability.

Section 454D provides that the State may recover a contribution from a local government for any liability indemnified under section 454C(1) in certain circumstances. The circumstances are: if the liability resulted from conduct that was engaged in other than in good faith and with gross negligence; if the local government engaged in conduct that they knew or should have known could have prejudiced the State's defence of a claim or a potential claim relating to the liability; or the local government did not reasonably cooperate with, and assist, the State to defend the claim that resulted in the liability. This section further provides that the amount of contribution recoverable will be determined by the court.

Section 454E provides that a local government is not indemnified in relation to civil liability of the local government under the *Workers' Compensation and Rehabilitation Act 2003*.

Section 454F provides that division 3 of new part 1A states the indemnity conditions with which a local government must comply in order to be indemnified by the State for an asbestos-related event.

Section 454G states that the local government must ensure an authorised person who exercises their powers under the Act in relation to an asbestos-related event has satisfactorily completed the training prescribed under a regulation.

Section 454H provides that a local government must comply with the *Public Health Act 2005* and any other laws relevant to an asbestos-related event, and any guideline the chief executive may make under subsection (2) about asbestos-related events. A guideline made under this section must be prescribed under a regulation and published on the department's website.

Section 454I sets out the record-keeping requirements for local government about any asbestos-related event. The intent of this section is to require a local government to make and keep records about any actions and information relating to an asbestos-related event that will assist in defending any future claim. This section also requires local government to make and keep records about a guideline made under section 454H. Local governments must ensure records are made and kept about an authorised person who exercises their powers under the *Public Health Act 2005* in relation to an asbestos-related event, including details of any asbestos-related training completed by the person.

The section goes on to provide that a local government must ensure records made about asbestos-related events and any asbestos-related training completed by authorised persons must be kept for at least 70 years after the day of the last action on the record. This is because of the long latency period between exposure to asbestos and the diagnosis of an asbestos-related disease (up to 50 years). As such, there may be a significant time delay between the management of an asbestos-related event by local government and an affected party seeking compensation for damages.

Section 454J provides that the chief executive of a local government may provide an annual certificate about the local government's compliance with the indemnity conditions in division 2 for asbestos-related events during that year. The annual compliance certificate must be in the approved form, be signed by the chief executive officer and verified by statutory declaration. These latter requirements are necessary because the certificate is taken to be evidence of compliance under section 454L. The indemnity will still apply (subject to the local government meeting the conditions for the indemnity in section 454C) if the local government does not provide an annual compliance certificate.

Section 454K provides that, if the chief executive receives an annual compliance certificate, the chief executive must give the chief executive officer of the local government a notice acknowledging receipt of the certificate.

Section 454L provides that the annual compliance certificate is, in the absence of evidence to the contrary, evidence of the matters stated in the certificate.

### Amendment of s 456 (Protecting prescribed persons from liability)

*Clause 44* amends section 456 to clarify that the protection from civil liability in section 456 does not apply to a prescribed person if section 454B(1) prevents civil liability attaching to the person or if the person is covered under the protection from civil liability in section 26B(4) of the *Public Service Act 2008*. This section also amends the meaning of a prescribed person in section 456 to remove those persons who are covered under the *Public Service Act 2008*.

### Amendment of sch 2 (Dictionary)

*Clause 45* amends the dictionary in schedule 2 of the Act to insert definitions in relation to asbestos-related civil liability for application throughout the Act.

## Part 7 Amendment of Radiation Safety Act 1999

### Act amended

*Clause 46* specifies that this part amends the *Radiation Safety Act 1999*.

### Amendment of s 47A (Banning of certain radiation practices)

*Clause 47* amends the definition of *prescribed radiation source* in section 47A to clarify that a prescribed radiation source means a radiation source prescribed under a regulation for this section. The clause also removes subsection (2) which provides that a solarium is taken to be a radiation apparatus, and removes the definition of 'solarium'.

At the time section 47A was included in the Act, it was necessary to clarify that a solarium was a radiation source, and that solaria would consequently be captured by this provision. It was also necessary to define 'prescribed radiation source' and 'solarium'. However, amendments to the *Radiation Safety Regulation 2010*, in regards to commercial solaria, will make these definitions redundant after 31 December 2014.

### Insertion of new s 50A

*Clause 48* inserts a new section 50A to clarify that a person may not apply for an Act instrument for a banned radiation source. Similarly, the chief executive may not issue an Act instrument for a banned radiation source. This provision aims to prevent any attempts to circumvent the prohibition on banned radiation sources (such as commercial solaria) by applying for a possession licence for, or an approval to acquire, a banned radiation source.

### Amendment of s 79 (Applications for renewal)

*Clause 49* amends section 79 to provide that the chief executive may accept an application for the renewal of a renewable Act instrument where the application is made within 30 days of the instrument's expiry. However, the chief executive must be satisfied that it is reasonable in the circumstances to accept the late application. Reasonable circumstances may include, for example, a failure or delay in the transmission of the application by post, or an unforeseen medical condition that has prevented the holder of an Act instrument from applying before the instrument expires.

### Insertion of new pt 14, div 5

*Clause 50* inserts a transitional provision for the records of the Radiological Advisory Council of Queensland. The new provision specifies that the records of the former Radiological Advisory Council of Queensland, are, and are taken to have always been, the records of the current Radiation Advisory Council.

### Amendment of sch 2 (Dictionary)

*Clause 52* amends the dictionary in schedule 2 to insert a definition for *banned radiation source*. A banned radiation source is defined by reference to section 47(1).

## Part 8 Amendment of Tobacco and Other Smoking Products Act 1998

### Act amended

*Clause 52* provides that this part amends the *Tobacco and Other Smoking Products Act 1998*.

### Insertion of new s 5A

*Clause 53* inserts new section 5A to provide a meaning of a *personal vaporiser* and *personal vaporiser related product*.

As the definition of personal vaporiser may, unintentionally capture a bong, hookah or ice pipe (which are dealt with separately under the *Tobacco and Other Smoking Products Act 1998*), section 5A specifically excludes these items from being a personal vaporiser or a personal vaporiser related product.

The definitions are intended to exclude items of a similar nature that are not intended to be used as a personal vaporiser, such as an asthma puffer.

### Replacement of pt 2, div 3, hdg (Supply of herbal cigarettes and loose smoking blends from coin operated vending machines)

*Clause 54* replaces the heading for part 2, division 3, to take into account that this division now captures personal vaporisers, in addition to herbal cigarettes and loose smoking blends.

### Amendment of s 18 (Prohibition on use of vending machine to supply herbal cigarettes and loose smoking blends)

*Clause 55* amends the heading for section 18, to refer to personal vaporisers and related products, and amends section 18 to prohibit the supply and sale of personal vaporisers and personal vaporiser related products from tobacco product vending machines. This section treats these products the same way as herbal cigarettes, and continues to limit vending machines to supplying only tobacco products.

### Amendment of s 25 (Definitions for pt 2A)

*Clause 56* amends the definition of *smoking product* in section 25 to include a personal vaporiser or a personal vaporiser related product. This amendment ensures these products are captured in provisions that regulate advertising, display and promotion of smoking products.

### Amendment of s 26R (Person must not smoke in enclosed place)

*Clause 57* amends section 26R to remove subsection (2)(d). A prohibition on smoking at all public and private correctional facilities in Queensland took effect from 5 May 2014, following amendments to the *Corrective Services Regulation 2006*. This is a consequential amendment that supports those smoking bans by removing the exemption to the prohibition on smoking in enclosed public places that currently applies to secure correctional facilities, as it is now redundant.

### Amendment of s 26VA (Definitions for pt 2BA)

*Clause 58* amends section 26VA to remove the definitions for motor vehicle, road and road-related area, as these definitions are moved to the schedule (dictionary) in a later clause.

### Insertion of new pt 2C, div 2A

*Clause 59* inserts a new division 2A (health facility land and school land) into part 2C. This division inserts new sections 26ZGA to 26ZGF.

Section 26ZGA provides that the new division does not apply to an enclosed place. This is to provide clarity about the provision under which a person commits an offence for smoking in an enclosed place on health facility land or school land.

Section 26ZGB sets out the definitions for the new division.

Section 26ZGC creates an offence for a person to smoke on health facility land or within five metres outside the boundary of health facility land. To do so carries a maximum penalty of 20 penalty units. However the prohibition on smoking within five metres of the boundary of health facility land does not apply to residential premises, business premises or a person in a motor vehicle, unless the vehicle is parked on a road or road-related area.

Section 26ZGD creates an offence for a person to smoke on school land or within five metres outside the boundary of school land. To do so carries a maximum penalty of 20 penalty units. However the prohibition on smoking within five metres of the boundary of school land does not apply to residential premises, business premises or a person in a motor vehicle, unless the vehicle is parked on a road or road-related area.

Section 26ZGE provides that a person who contravenes sections 26ZGC or 26ZGD must comply with a direction to stop smoking. Failure to do so is an offence carrying a maximum penalty of 20 penalty units.

Section 26ZGF specifies that sections 26ZM, 26ZN(a), 26ZO and 26ZP apply to the administration and enforcement of this division as if a reference to a matter in those sections were a reference to a matter under this division and an offence in those sections were a reference to an offence under this division. The purpose of this amendment is to enable local governments to enforce the smoking bans at schools and hospitals.

### Amendment of s 26ZS (Supply of objects resembling tobacco products)

*Clause 60* amends section 26ZS to provide that the prohibition on the supply of objects resembling tobacco products does not apply to personal vaporisers. This is because it is not intended to ban the supply of personal vaporisers, but rather to regulate the display, advertising and promotion of these products in the same way that other smoking products are regulated in retail environments.

### Amendment of s 28 (Appointment)

*Clause 61* amends section 28 to enable the health service chief executive to appoint an appropriately qualified person as a *health service authorised person* for the purposes of investigating, monitoring and enforcing compliance with the smoking bans on health facility land. This amendment further specifies that the health service authorised person appointed under subsection (4) may only enforce compliance on land managed by the Service to which the person's appointment refers (so the health service authorised person is not permitted to enforce the bans on health facility land managed by another HHS).

### Insertion of new s 31A

*Clause 62* inserts a new section 31A that states part 3, division 2 does not apply to a health service authorised person. The intent is that the powers of other authorised persons, for example the power to enter a place with consent or under warrant, do not apply to health service authorised persons. This is because the enforcement provisions for health service authorised persons are limited to only the smoking bans on and around public health facility land (which is land on which an HHS provides a health service), and the powers in part 3, division 2 of the Act are not relevant to enforcement of those smoking bans.

### Insertion of new s 37C

*Clause 63* inserts new section 37C to specify that part 3, division 3 of the Act, other than sections 38 and 40A, does not apply to a health service authorised person. This section goes on to clarify that a health service authorised person may only exercise a power under section 38 or 40A. This ensures that, while enforcing smoking bans on and around public health facility land (which is land on which an HHS provides a health service), a health service authorised person is empowered to require name and address of a person committing a smoking offence and is empowered to direct the person to stop smoking.

### Amendment of s 40A (Power to direct person to stop smoking)

*Clause 64* amends section 40A to extend the power to direct a person to stop smoking, to the new offences of smoking on health facility land and school land in sections 26ZGC and 26ZGD.

### Insertion of new s 40AB

*Clause 65* inserts new section 40AB to state that part 3, division 4 of the Act does not apply to a health service authorised person. The intent is that the powers of other authorised persons, for example the power to seize evidence, do not apply to health service authorised persons. This is because the enforcement provisions for health service authorised persons are limited to only the smoking bans on and around public health facility land (which is land on which an HHS provides a health service), and the powers in part 3, division 4 of the Act are not relevant to enforcement of those smoking bans.

### Insertion of new s 44BA

*Clause 66* inserts new section 44BA to specify that part 3, division 5, other than sections 45, 46, 49 and 50, does not apply to a health service authorised person. The intent is that the powers of other authorised persons, for example the power to issue an improvement notice, do not apply to health service authorised persons. This is because the enforcement provisions for health service authorised persons are limited to only the smoking bans on and around public health facility land (which is land on which an HHS provides a health service), and the powers in part 3, division 5 of the Act are not relevant to enforcement of those smoking bans. However, the powers in relation to section 45 (offence for a person to provide false or misleading information), section 46 (offence for a person to give a false, misleading or incomplete document), section 49 (offence to impersonate an authorised person) and section 50 (offence to obstruct an authorised person) will apply to a health service authorised person.

### Amendment of sch (Dictionary)

*Clause 67* amends the schedule (dictionary) of the *Tobacco and Other Smoking Products Act 1998* to insert or amend definitions for application throughout the Act.

## Part 9 Amendment of Transplantation and Anatomy Act 1979

### Act amended

*Clause 68* specifies that this part amends the *Transplantation and Anatomy Act 1979*.

### Amendment of s 4 (Interpretation)

*Clause 69* amends section 4 to include a definition for the term ‘trading’. ‘Trading’ is defined by reference to the new section 39.

### Insertion of new s 39

*Clause 70* inserts a new section 39. For the purposes of part 7 of the Act, the new section defines trading in relation to tissue. The definition reflects the scope of activities mentioned in sections 40(1), 41(1), and 42(1).

### Amendment of s 42A (Person who owns a prescribed tissue bank may charge amount to recover certain costs)

*Clause 71* amends section 42A(1) and 42A(2) to clarify that a tissue bank prescribed under section 42A(1) can agree to sell, offer to sell, hold out to sell, or inquire as to whether a person is willing to buy donated tissue.

The clause also amends section 42A(3) to clarify that a potential buyer can agree to buy, offer to buy, hold out as being willing to buy tissue from the tissue bank, or inquire as to whether the tissue bank is willing to sell donated tissue.

The exemptions apply only to actions associated with buying and selling for a cost recovery amount.

Since holding out, inquiring, offering and agreeing to buy and sell are necessary steps towards charging and paying an amount for tissue (as authorised by section 42A prior to these amendments), the amendments to section 42A are clarifying in nature.

### Insertion of new ss 42AA and 42AB

*Clause 72* inserts a new section 42AA and 42AB into the Act.

Section 42AA relates to the trading of tissue for therapeutic, medical or scientific purposes.

Sub-section (1) provides that sections 40 (Unauthorised buying of tissue prohibited), 41 (Advertising relating to buying of tissue restricted) and 42 (Unauthorised selling of tissue prohibited) do not apply to the trading of tissue if –

a) the tissue has been subjected to processing or treatment; and

b) the trading of the tissue is for a therapeutic purpose, medical purpose or scientific purpose;

c) the tissue is a biological or medical device included in the register under the *Therapeutic Goods Act 1989* (Cwlth), or a registered good under the *Therapeutic Goods Act 1989* (Cwlth); and

d) the tissue is not relevant tissue.

Sub-section (2) defines two terms for the purposes of section 42AA.

'Register' is defined to mean the Australian Register of Therapeutic Goods kept under the *Therapeutic Goods Act 1989* (Cwlth), section 9A.

'Relevant tissue' is defined as tissue that is stored at a tissue bank under section 42A or tissue mentioned in section 42AB(1). Tissue banks prescribed under section 42A will remain subject to the restrictions in that section; they will able to charge only amounts to recover reasonable costs associated with removing, evaluating, processing, storing and distributing donated tissue. Trade in tissue mentioned in the new section 42AB(1) will be exempted by that section from the operation of sections 40, 41, and 42, but will be subject to different conditions.

Subsection 42AA(1)(c) refers to tissue that is a *biological*, *medical device*, or *registered good*. For the meaning of these terms, it is necessary to refer to the *Therapeutic Goods Act 1989* (Cwth). A summary of these terms, and related terms, is provided below.

Under the *Therapeutic Goods Act 1989* (Cwth), a therapeutic good can be supplied in Australia if, *inter alia*, it is included in the Australian Register of Therapeutic Goods (ARTG). The ARTG has four parts – a part for *biological*, a part for *medical devices*, a part for *registered goods*, and a part for *listed goods*.

A *biological* is a thing that comprises, contains or is derived from human cells or human tissues. Biologicals are assessed by the TGA under the *Regulatory Framework for Biologicals* (the Framework). The Framework was introduced in 2011, and is a comprehensive mechanism that enables the assessment and control of therapeutic goods produced by medical supply companies, both local and international.

Biologicals assessed by the TGA under the Framework as being safe for use and delivering a therapeutic benefit are included on the part of the ARTG for biologicals.

However, if the administering Commonwealth Secretary declares a particular biological not to be a biological, the biological is regulated by the TGA as either a *medicine* (ie. a registered or listed good) or a *medical device*. Biologicals declared not to be biologicals include diagnostic samples, blood and blood components, and biological medicines (including vaccines and plasma-derived products).

Also, if the administering Commonwealth Secretary declares a therapeutic good not be a therapeutic good under section 7 of the *Therapeutic Goods Act 1989 (Cwlth)*, the good is not regulated under that Act. Goods declared not to be therapeutic goods include fresh viable organs, bone marrow and cord blood, and reproductive tissues that have not been processed (other than by freezing). These are subject to the existing provisions of the *Transplantation and Anatomy Act 1979*, and will be subject to the amendments detailed above.

*Medical devices* include instruments, apparatus, appliances and materials for diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability (for example, antibiotic bone cements) that have been evaluated by the TGA and included on the part of the register for medical devices.

*Registered goods* are higher-risk therapeutic goods (including some medicines, but not biologicals or medical devices) that have been evaluated by the TGA for quality, safety and efficacy, and are included in the part of the ARTG for registered goods.

*Listed goods* are lower-risk therapeutic goods (including medicines, but not biologicals or medical devices) that contain pre-approved, low-risk ingredients, and are included in the part of the ARTG for listed goods.

Section 42AA intends to capture tissue-based therapeutic goods that are included in the ARTG as *registered goods*, *biologicals* or *medical devices*, but not *listed goods*. This is to ensure that tissue-based goods which have not been evaluated by the TGA for safety, quality and efficacy are not exempted from the trading restrictions in the *Transplantation and Anatomy Act 1979*.

For section 42AA(b), it is intended that 'therapeutic purpose', 'medical purpose' and 'scientific purpose' can include diagnosis and diagnostic testing.

For section 42AA(1)(c), it is intended that tissue includes tissue which is part of a 'kit' that constitutes a therapeutic good under section 7B of the *Therapeutic Goods Act 1989* (Cwth).

Clause 72 also introduces new section 42AB into the *Transplantation and Anatomy Act 1979*.

The new sub-section 42AB(1) provides that sections 40, 41 and 42 do not apply to the trading of tissue if the trading of the tissue is carried out by, or with –

a) an exempt entity, or the Commonwealth for the benefit of an exempt entity; and

b) the tissue is the subject of an agreement between the exempt entity and the Commonwealth or the State.

Sub-section (2) defines a number of terms for the purposes of section 42AB.

'Blood products' is defined by reference to paragraph (a) of the definition of that term in section 3 of the *National Blood Authority Act 2003* (Cwth).

'Exempt entity' is defined to mean:

a) for blood products, an entity mentioned in the national products price list as a supplier; or

b) for tissue other than blood products, an entity that –

   (i) is a party to an agreement with the Commonwealth or the State for the buying and selling of tissue; and

   (ii) is prescribed in a regulation.

'National Blood Agreement' is defined by reference to the meaning of that term in section 3 of the *National Blood Authority Act 2003* (Cwth).

'National product price list' is defined to mean the annual national products price list approved by the Ministerial Council under the *National Blood Agreement*. This list is published by the National Blood Authority.

Importantly, subsection (1) operates to exempt the trading of tissue from the operation of sections 40 (Unauthorised buying of tissue prohibited) and 42 (Unauthorised selling of tissue prohibited). For the exemption to apply to a purchase or sale, an exempt entity must be either the buyer or seller. However the other party to an exempted purchase or sale does not commit an offence under sections 40 or 42 merely by being party to the exempted transaction, regardless of whether the other party is also an exempt entity.

Sub-section (1) also operates to exempt the Commonwealth trading for the benefit of an exempt entity, for example, by making direct payments to a third party for tissue which the third party has agreed to supply to an exempt entity.

It is also important to note that the scope of the sub-section (1) exemption is limited by paragraph (b) to tissue which is the subject of the agreement with the Commonwealth or State. The mere existence of an agreement relating to one type of tissue does not authorise trade of other types of tissue or tissue generally.

The new section has substantially the same effect as section 40(3) in Part VII of the draft legislation in the Australian Law Reform Commission Report (ALRC), *Human Tissue Transplants* 1977 (No. 7), Appendix 4, on which the Act is largely based. It is consistent with the recommendations of the ALRC report, and with the following corresponding interstate provisions, also based on the ALRC model legislation:

- NSW: *Human Tissue Act 1983* - section 32(2)
- SA: *Transplantation and Anatomy Act 1983* – section 35(3)
- Tas: *Human Tissue Act 1985* – section 27(2)
- NT: *Transplantation and Anatomy Act* – section 22E(3)
- ACT: *Transplantation and Anatomy Act 1978* – section 44(2).

## Insertion of new s 44A

*Clause 73* inserts new section 44A.

Sub-section (1) of this new section limits the application of section 44A to human eggs, human sperm or human embryos, within the meaning of the *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003* (RIHE Act)

The scope of sub-section (1) is determined by reference to the meaning of the terms 'human eggs', 'human embryos' and 'human sperm' in the RIHE Act. The terms 'human embryos' and 'human sperm' are defined in the RIHE Act. The term 'human egg' is not defined in either new section 44A or the RIHE Act, and so it takes its normal meaning in both contexts. The use of the term 'human egg' in this section is not intended to convey a different meaning to the term 'ova' in section 8 of the *Transplantation and Anatomy Act 1979*.

Sub- section (2) provides if there is any inconsistency between the *Transplantation and Anatomy Act 1979* and the RIHE Act, the RIHE Act is to prevail, but only to the extent of the inconsistency.

## Insertion of new s 51A

*Clause 74* inserts new section 51A, a general power for the Minister to delegate powers and functions under the Act to an appropriately qualified public service employee or health service employee.

The new section 51A should be read in conjunction with section 27A of the *Acts Interpretation Act 1954*.