

2022

**THE LEGISLATIVE ASSEMBLY FOR THE
AUSTRALIAN CAPITAL TERRITORY**

HEALTH LEGISLATION AMENDMENT BILL 2022

**EXPLANATORY STATEMENT
and
HUMAN RIGHTS COMPATIBILITY STATEMENT
(*Human Rights Act 2004, s 37*)**

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MLA**

Health Legislation Amendment Bill 2022

EXPLANATORY STATEMENT

This explanatory statement relates to the Health Legislation Amendment Bill 2022 (the Bill) as presented to the Legislative Assembly. It has been prepared in order to assist the reader of the Bill and to help inform debate on it. It does not form part of the Bill and has not been endorsed by the Assembly.

The Bill **is not** a Significant Bill. Significant Bills are bills that have been assessed as likely to have significant engagement of human rights and require more detailed reasoning in relation to compatibility with the *Human Rights Act 2004*.

The Statement is to be read in conjunction with the Bill. It is not, and is not meant to be, a comprehensive description of the Bill. What is said about a provision is not to be taken as an authoritative guide to the meaning of a provision, this being a task for the courts.

OVERVIEW OF THE BILL

Legislation to be amended

This Bill amends the following:

- the *Tobacco and Other Smoking Products Act 1927* (TOSP Act);
- the *Medicines Poisons and Therapeutic Goods Act 2008* (MPTG Act); and
- the *Transplantation and Anatomy Act 1978* (TA Act).

Proposed changes

The Bill amends the TOSP Act to allow compliance testing to occur for sales of e-cigarettes to minors; to clarify that no smoking products may be sold via vending machine and to exempt community pharmacists from the requirement to source nicotine vaping products from a wholesaler who holds an ACT Tobacco licence.

The Bill amends the MPTG Act to extend the application of Commonwealth therapeutics goods laws in the ACT. The change will enable the Therapeutic Goods Administration (TGA) to take action against sole traders operating wholly within the ACT in relation to nicotine vaping products (aka nicotine containing e-cigarettes) and other matters arising under the *Therapeutic Goods Act 1989 (Cwlth)*.

The Bill amends the TA Act to resolve technical legal compatibility issues between the TA Act and the *Births, Deaths and Marriages Registration Act 1997* (BDMR Act). The change will enable the issuing of verifying information to confirm a deceased individual's donor status without concern of conflict between the TA Act and the BDMR Act.

COSTS AND BENEFITS STATEMENT

The Bill makes technical amendments. This Bill has no financial implications.

CONSISTENCY WITH HUMAN RIGHTS

This section provides an overview of the human rights which may be engaged by the Bill. The proposed amendments in the Bill have been considered in the context of the objects of the *Human Rights Act 2004* (HRA).

Rights Promoted

The Bill does engage and promote the right to life through facilitating the use of regulatory interventions against smoking products that are associated with harm. The Bill further promotes the right to life by enabling open communications regarding organ and tissue donation.

The right to life

The right to life has been interpreted by the United Nations' Human Rights Committee as meaning that States must take appropriate measures to address the general conditions in society that may give rise to threats to the right to life or prevent individuals from enjoying their right to life with dignity and that environmental degradation and climate change are a threat to present and future generations' enjoyment of the right to life. Thus, it has stated that 'implementation of the obligation to respect and ensure the right to life, and in particular life with dignity, depends, inter alia, on measures taken by States parties to preserve the environment and protect it against harm, pollution and climate change caused by public and private actors.'¹

There is a growing evidence base that demonstrates the public health harms associated with e-cigarette use. As such, regulatory measures to ensure existing restrictions on traditional smoking products (i.e. tobacco products) can be applied to newer or novel smoking products supports the right to life. This is particularly relevant in the context of young people, who may be more vulnerable to the health impacts of smoking products such as e-cigarettes due to physical factors (such as their developing lungs) and unawareness of the potential for addiction.

The Bill promotes the right to life through minor and technical updates to extend the application of Commonwealth therapeutic goods laws in the ACT. The change will enable the TGA to take action against sole traders operating wholly within the ACT in relation to nicotine vaping products (aka nicotine containing e-cigarettes) and other matters arising under the *Therapeutic Goods Act 1989* (Cwlth).

¹ UN Human Rights Committee (HRC), [General comment no. 36, Article 6 \(Right to Life\)](#), 3 September 2019, CCPR/C/GC/35.

Authorising the TGA to undertake this limited regulatory action does not directly engage the HRA as Australian Government employees, in exercising functions of a Commonwealth law, are not subject to the HRA (in particular the right to privacy and reputation) in making regulatory decisions. In facilitating possible TGA compliance activity against sole traders and individuals in the ACT, it is noted that any privacy impacts would be reasonably limited to activities concerning the *Therapeutic Goods Act 1989 (Cwlth)* and that privacy protections are already afforded to sole traders under the *Privacy Act 1988 (Cwlth)*. Privacy complaints against Australian Government agencies or employees may also be investigated by the Office of the Australian Information Commissioner.

This Bill further promotes the right to life through acknowledgment of the significant gift of organ and tissue donation. It enables the clinical organ and tissue donation service (DonateLife ACT) to confirm donor status to the requesting next of kin of a deceased individual in order to facilitate the Tissue Donation Certificate Scheme under s 38A of the BDMR Act.

The Bill will support DonateLife ACT to comply with the relevant disclosure section of the TA Act when doing so.

The Bill engages but does not limit the deceased's next of kin's right to privacy. It is, however, the next of kin's decision to disclose the information, and that consent addresses any potential interference with the right to privacy.

Rights Limited

The measures in the Bill may engage and limit the right to protection of the family and children (section 11 HRA) and the right to presumption of innocence (section 22(1) HRA).

The preamble to the Human Rights Act 2004 (HR Act) notes that few rights are absolute and that they may be subject only to the reasonable limits in law that can be demonstrably justified in a free and democratic society. Section 28(1) of the HRA provides that in deciding whether a limit on human rights is reasonable, all relevant factors must be considered, including the following:

- a) the nature of the right affected;
- b) the importance of the purpose of the limitation;
- c) the nature and extent of the limitation;
- d) the relationship between the limitation and its purpose; and
- e) any less restrictive means reasonably available to achieve the purpose the limitation seeks to achieve.

Protection of family and children (s 11 HRA)

Nature of the right and the limitation (ss 28(2)(a) and (c))

Under section 11 of the HRA, every child has the right to the protection needed by the child because of being a child, without distinction or discrimination of any kind. Children have

special rights under human rights law taking into account their particular vulnerabilities. Expanding a regulatory and enforcement scheme that provides for covert and randomised operations involving ‘undercover’ children to include e-cigarettes, could be a greater limitation on the rights of children involved than that which is currently contemplated by existing provisions of the TOSP Act.

Legitimate purpose (s 28(2)(b))

The amendment is directed at the legitimate aim of protecting young people from the harmful effects of e-cigarettes by limiting the availability of these products to be bought and sold to children and young people.

Rational connection between the limitation and the purpose (s 28(2)(d))

Sale of e-cigarettes to people under the age of 18 is prohibited by the TOSP Act, and covert, ‘undercover’ operations are intended to increase compliance with this prohibition. The amendment is therefore rationally connected to a legitimate aim.

Proportionality (s 28(2)(e))

It is considered that the limitation on the rights of individual children involved in the compliance testing is proportionate and reasonable having regard to the existing protections for young people who participate in the operations. Safeguards include provision of procedures to ensure the welfare, health and safety and privacy as well as the requirement to obtain informed consent of the young person and/or their guardian. With these safeguards in mind and given the substantial protection to children and young people from tobacco and smoking related harm, any limitation on children’s rights by the amendment to increase compliance with a ban on e-cigarette sales to people under 18, is considered reasonable and proportionate.

Right to presumption of innocence (s 22(1) HRA)

Nature of the right and the limitation (ss 28(2)(a) and (c))

TOSP Act

Under section 22 of the HRA, everyone charged with a criminal offence has the right to be presumed innocent until proven guilty according to law. The presumption of innocence means that the prosecution has the burden of proving ‘beyond reasonable doubt’ that the accused committed the charged offence.

Under section 67(2) of the TOSP Act, it is a strict liability offence for a retail tobacconist to obtain a smoking product from someone who is not the holder of a wholesale tobacco merchant’s licence. The Bill amends section 67 so that the offence is not made out if the holder of a retail tobacconist’s licence operates a community pharmacy and obtains a personal vaporiser or related product that is a medicine from someone who is not the holder of a wholesale tobacco merchant’s licence. This creates an exception to the general offence

provision, but the defendant bears the evidential burden. Per the ‘Guide to Framing Offences’, an evidential burden places the defendant in the position of presenting, or pointing to, evidence that suggests a reasonable possibility that the defence can be established. Requiring the defendant to raise facts in this way amounts to a reversal of the burden of proof and this may engage and limit the right to be presumed innocent.

Legitimate purpose (s 28(2)(b))

Although the right to be presumed innocent may be limited by this amendment, the reverse burden is for the legitimate purpose of ensuring pharmacies that supply medicines for the public can purchase medicinal personal vaporisers (or related products) from someone who does not hold a wholesale tobacco merchant’s licence.

Rational connection between the limitation and the purpose (s 28(2)(d))

There is a rational connection between the requirement for a community pharmacy to prove that the product purchased for medicine because the facts of the purchase are likely to be uniquely within the knowledge of the defendant and their evidence would serve to prevent unnecessary prosecution.

Proportionality (s 28(2)(e))

The amendment is reasonable and proportionate limitation on the right to be presumed innocent. The offence carries a maximum penalty of 50 penalty units which is appropriate to the seriousness of the offence and provides sufficient deterrent to improperly obtaining vaporisers. There is also an existing safeguard within section 67 in that the defence of ‘mistake of fact’ is available to the defendant. This would allow a community pharmacy, for example, to argue that they had a reasonably held belief that the product they were purchasing was a medicine.

TA Act

The right to be presumed innocent is similarly engaged by the amendment to section 49 of the TA Act, which creates an exception to the offence of disclosing identifying personal information of people who have donated tissue, in certain circumstances.

In this instance, the exception serves the legitimate purpose of facilitating the policy intent of section 38A of the BDMR Act, by ensuring that people involved in providing Donor Confirmation Letters at the request of next of kin of deceased tissue donors are assured they will not be prosecuted under section 49 of the TA Act where they provide that material in accordance with section 38A of the BDMR Act. Although casting the provision as an exception may engage and limit the right to be presumed innocent, any limitation is reasonable and proportionate as it will provide greater protections from prosecution by excluding people who are complying with the BDMR Act. There is also an existing safeguard in that the prosecution retain the burden of proof in all other elements of the offence.

Health Legislation Amendment Bill 2022
Human Rights Act 2004 - Compatibility Statement

In accordance with section 37 of the *Human Rights Act 2004* I have examined the **Health Legislation Amendment Bill 2022**. In my opinion, having regard to the Bill and the outline of the policy considerations and justification of any limitations on rights outlined in this explanatory statement, the Bill as presented to the Legislative Assembly **is** consistent with the *Human Rights Act 2004*.

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Shane Rattenbury MLA
Attorney-General

CLAUSE NOTES

Part 1 Preliminary

Clause 1 Name of Act

This is a technical clause that names the short title of the Bill upon its passage in the ACT Legislative Assembly. The name of the Act will be the *Health Legislation Amendment Act 2022*.

Clause 2 Commencement

This clause provides that the Act will commence on the day after its notification day.

Clause 3 Legislation amended

This clause lists the legislation amended by the Bill. The Bill will amend the *Medicines, Poisons and Therapeutic Goods Act 2008*, the *Tobacco and Other Smoking Products Act 1927* and the *Transplantation and Anatomy Act 1978*.

Part 2 Medicines, Poisons and Therapeutic Goods Act 2008

Clause 4 Application of Commonwealth therapeutic goods laws to ACT New section 157(3)

This clause inserts a new section 157 (3) that extends Commonwealth therapeutic goods laws to apply to a person who is not a corporation (e.g. a sole trader) within the ACT. The new section enables officers authorised under the *Therapeutics Goods Act 1989 (Cwlth)* to take action against sole traders operating wholly within the ACT where these traders are breaching the Therapeutics Goods Act.

Part 3 Tobacco and Other Smoking Products Act 1927

Clause 5 What is a *compliance test*? Section 42B (1) (a)

This clause removes the term ‘tobacco products’ from section 42B (1) (a) and substitutes the term ‘smoking products’ in its place. This substitution allows compliance testing for sales to a minor to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

Clause 6 **Section 42B (1) (b)**

This clause removes the term ‘tobacco product’ from Section 42B (1) (b) and substitutes the term ‘smoking product’ in its place. This substitution allows compliance testing for sales to minors to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

Clause 7 **Approval of compliance testing programs: Section 42C (2) (a)**

This clause removes the term ‘tobacco products’ from section 42C (2) (a) and substitutes the term ‘smoking products’ in its place. This substitution allows compliance testing for sales to minors to be conducted for all products captured within the definition ‘smoking product’ under section 3A of the *Tobacco and Other Smoking Products Act 1927* (e.g. herbal products, personal vaporiser products, etc).

Clause 8 **No vending machines authorised: Section 49A**

This clause removes the term ‘tobacco products’ from section 49A and substitutes the term ‘smoking products’ in its place. This substitution clarifies that no smoking products may be sold by vending machine.

Clause 9 **Retail tobacconist must obtain smoking products from licensed wholesaler**

New section 67 (4) and (5)

This clause inserts two new sections.

Section 67(4) exempts a community pharmacy from the requirement to obtain smoking products, that are also medicines, from a wholesaler who holds an ACT Tobacco licence.

Section 67(5) gives definitions for the terms ‘community pharmacy’ and ‘medicine’ as used in Section 67 (4).

Part 4 **Transplantation and Anatomy Act 1978**

Clause 10 **Disclosure of information**

New section 49 (4) (aa)

This clause inserts a new section 49 (4) (aa) to provide that offences under sections 49 (1) and 49 (2) do not apply to a next of kin of a deceased person for the purposes of section 38A (3) of the *Births, Deaths and Marriages Registration Act 1997*. Section 38 A (3) states that requests must be in writing and include information verifying that the deceased person was a tissue donor. The effect of this new section is that information verifying tissue donation by a deceased person can be disclosed to a next of kin without engaging an offence under sections 49 (1) and 49 (2) of the *Transplantation and Anatomy Act 1978*.