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THE LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS AMENDMENT BILL 2018

EXPLANATORY STATEMENT

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Overview

The objective of the *Medicines, Poisons and Therapeutic Goods Act 2008* (the Act) is to promote and protect public health and safety by minimising medicinal misadventure with, and diversion of, regulated substances, and the manufacture of regulated substances that are subject to abuse.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (the Regulation) provides the detail for the regulatory framework established by the Act. The Regulation sets out which health professionals are able to prescribe, administer and dispense a medicine, and conditions relating to such dealings. Some provisions of the Regulation also prescribe additional information required for licences or authorisations.

This Bill proposes changes to the Act and the Regulation to establish a regulatory framework that would allow for authorised people to remotely access, use and disclose information on the ACT's monitored medicines database as a public health and clinical support tool. These changes also establish rules concerning what information may be stored in the database, as well as roles and responsibilities concerning the management, integrity, security and use of database information. The Bill also introduces several new offence provisions to limit the Bill's impact on personal privacy by stipulating that any unauthorised access, use or disclosure of database material be subject to penalty. The changes would also enable the ACT to enter into arrangements with other jurisdictions to facilitate the sharing of database information under any cross-jurisdictional public health initiative concerning the prescription and supply of scheduled medicines.

Driving the need for these changes is the adverse health effects relating to the misuse, abuse and diversion of scheduled medicines which affects the entire ACT community and places an increased burden on the health system. To help address the public health impacts associated with scheduled medicines, the *National Drug Strategy 2017-2026* and the *National Pharmaceutical Drug Misuse Framework for Action 2012-2015* have recommended implementing systems for the real-time monitoring of prescription medications so that prescribers can prevent patients inappropriately accessing harmful and substantial quantities of medications. Implementing systems for the real-time monitoring of prescription medicines has also been recommended by several State and Territory Coroners, including Coroner Hunter OAM in her report into the Inquest into the Death of Paul Fennessy.

The misuse and abuse of pharmaceutical medicines is a recognised national issue with the National Drug Strategy Household Survey 2016 reporting that 4.8 per cent of Australians had misused a pharmaceutical drug, especially prescription opioids, in the last 12 months. Victoria has also reported an increase in the number of overdose deaths involving prescription medicines from 295 in 2009 to 372 in 2016. In 2016, Victorian overdose deaths concerning pharmaceutical medicines surpassed fatalities attributed to illicit drugs or the road toll. Data from the National Drug Strategy 2017-2026 also notes that Australia has seen an increase in the prescription and use of pharmaceutical medicines (particularly opioids) with the supply of oxycodone and fentanyl increasing 22 fold and 46 fold respectively between 1997 and 2012. Consistent with these trends, hospital admissions associated with prescription opioid poisoning have risen substantially.

Tasmania is currently the only Australian jurisdiction to have implemented a real-time prescription monitoring framework that allows health professionals to remotely access limited patient information to guide the prescription and supply of certain medicines. Since implementation of this framework, opioid-related deaths in Tasmania has reportedly decreased from 32 in 2007 to approximately 20 in 2013 and 2014.

A monitored medicines database, as established by this Bill would allow relevant health practitioners limited access to their patient's health information to decide whether to prescribe or supply a controlled medicine or other scheduled medicine as declared by the Minister. All states and territories have established regulatory controls on the prescription and supply of controlled drugs. Controlled drugs (referred to as controlled medicines in the ACT) are substances classified under Schedule 8 of the Commonwealth Poisons Standard. The ACT adopts the Poisons Standard under the Act. Controlled medicines are substances that require additional controls on their public access due to their increased risk of dependency, abuse, misuse and/or diversion. Commonly known examples of controlled medicines include oxycodone, morphine, methadone and dexamfetamine.

The Chief Health Officer (CHO) would have responsibility for administering the monitored medicines database, including making any corrections to the database to keep the database accurate and up-to-date. Information to be included in the monitored medicines database is currently restricted to information concerning the approval to prescribe and supply controlled medicines. This information is currently collected by the CHO and stored in a secure database known as the Drugs and Poisons Information System (DAPIS) as part of the Act's existing framework. The establishment of the monitored medicines database will formalise the use of DAPIS as an ACT Government database and allow for its contents to be accessed, used and disclosed by authorised persons under specified circumstances as a public health protection tool. Secure remote access to the ACT's DAPIS database is currently provided for by a secure web-portal known as DORA (DAPIS Online Remote Access).

Authorised persons would include people who deal with controlled medicines and declared monitored medicines as part of their professional scope of practice and employment such as doctors, intern doctors, pharmacists, nurse practitioners, and any other person authorised by the CHO under an Access Authority.

Part 1 of this Bill contains the preliminary and formal provisions of the Bill, such as its proposed commencement. The clauses in Part 2 of the Bill amend or insert sections of the Medicines, Poisons and Therapeutic Goods Act 2008, whereas the clauses in Part 3 amend or insert sections of the Medicines, Poisons and Therapeutic Goods Regulation 2008.

A detailed explanation of each clause of the Bill follows. Discussion of limitations on human rights are outlined under the Human Rights Considerations heading below.

Clauses

Part 1 Preliminary

Clause 1 Name of Act

The first clause declares the name of the Act that is to be created to be the Medicines, Poisons and Therapeutic Goods Amendment Bill 2018.

Clause 2 Commencement

Pursuant to this provision, the *Medicines, Poisons and Therapeutic Goods Amendment Act 2018* (the Amendment Act) is to commence on the day after its notification day.

Due to the operation of section 75(1) of the *Legislation Act 2001* (the Legislation Act) the naming and commencement provisions of this Act, clauses 1 and 2, commence automatically on the day the Act is notified. A note to that effect is included in the provision (note 1).

Clause 3 Legislation amended

This provision alerts the reader that the Amendment Act amends both the Act and the Regulation.

When notified, this Bill becomes the Amendment Act, which upon commencement will alter the Act and the Regulation in accordance with the provisions contained in this Bill. The Amendment Act will then be immediately repealed.

Consequentially, from the date that the Amendment Act commences, a new republication of the Act and the Regulation will be available.

Part 2 Medicines, Poisons and Therapeutic Goods Act 2008

Clause 4 Supply of certain declared substances – information for Chief Health Officer

Section 31 (1) (a) and 31 (2) (a)

Section 31 of the Act contains an offence about failing to give information to the CHO regarding the supply of certain declared substances. Currently the section refers to ‘controlled medicines’.

This clause replaces references to a ‘controlled medicine’ within section 31 of the Act with the term ‘monitored medicine’. This change is purely a consequential change to be in keeping with the introduction of the concept of a ‘monitored medicine’ by clause 5 of this Bill. The substituted reference has no impact on the operation of the offence provision contained within section 31 of the Act.

Clause 5 New chapter 6A

This clause provides for the key provisions of this Bill, with the insertion of a new Chapter 6A into the Act. The focus of the new Chapter is apparent from the title; 'Monitored medicines database'. The new Chapter consists of nine sections. To fit in between existing provisions of the Act, the new sections have been numbered 97A through to 97H. The details of the new provisions are explained below.

97A Meaning of monitored medicine

New Section 97A details the definition of 'monitored medicine' and that is to have application throughout all of the Act

Subsection 1 provides that a monitored medicine is a controlled medicine, or a medicine declared by the Minister, by disallowable instrument, to be a monitored medicine.

A 'controlled medicine' is defined in section 11(2) of the Act as a medicine to which Schedule 8 of the Poisons Standard applies. Such medicines, often referred to simply as 'Schedule 8 medicines' or 'controlled drugs', include the opioids fentanyl, methadone, morphine and oxycodone. As the Poisons Standard explains, these medicines are tightly controlled to "reduce abuse, misuse and physical and psychological dependence".

Declaring other medicines to be monitored medicines allows the Minister to require the monitoring of medicines not listed in Schedule 8 of the Poisons Standard, should there be a perceived need.

The making of such a declaration may require the development of a Regulatory Impact Statement (as RIS) per Part 5.2 of the *Legislation Act 2001*, and approval by the Executive in the form of a signature by the Minister. The requirements for tabling with the Legislative Assembly, and being potentially subject to disallowance by the Legislative Assembly operates as they normally would.

97B Definitions – ch 6A

This provisions inserts new definitions used by Chapter 6A relating to the operation and use of the monitored medicines database.

This clause inserts the definition for an Approved data source entity to mean an entity engaged by another jurisdiction to collect, assess, store or otherwise deal with information about monitored medicines. This may include agreements with data collection entities such as prescription exchange services, or a national data exchange as provided by the Commonwealth or another state or territory government, concerning monitored medicines information.

It is necessary that such engagements be recognised in legislation to provide flexibility in relation to future developments in eHealth information technology, and as required to enable a future national system for real-time prescription monitoring.

97C Monitored medicines database – main purpose

New Section 97C states that the purposes of the monitored medicines poisons database are to monitor, and evaluate the supply of monitored medicines to a person and support the exercise of the CHO's functions. The monitored medicines database also is seen to support the main objects of the Act to promote public health and safety relating to the use of regulated substances.

97D Monitored medicines database – scope

New Section 97D provides that the CHO may keep the monitored medicines database to record information relating to monitored medicines, and establishes an obligation on the CHO to correct any known error or omission in the database. This section also outlines what information may be kept on the database including information relating to monitored medicines including any supply, approval to prescribe a monitored medicine, information from another jurisdiction or approved data source entirety, and information prescribed by regulation.

97E Monitored medicines database – chief health officer functions

New Section 97E sets new functions for the CHO in relation to the monitored medicines database. These functions include collecting and storing information on the database, and entering into arrangements with the Commonwealth, other States or Territories and any approved data source entity engaged by another Australian jurisdiction in relation to the provision of information to or from the database. This is necessary to enable cross-border information sharing, and in case of a future national system for real-time prescription monitoring.

This section also sets new functions for the CHO to use the monitored medicines database to monitor, promote and protect public safety through the issue of alerts or notifications, facilitate public health research, administer the database and its functions and ensure compliance with the Act.

97F Monitored medicines database – access and use by relevant health practitioners

New Section 97F provides for relevant health practitioners to access and use information held on the monitored medicines database. The CHO will have responsibility for facilitating and overseeing relevant health practitioner's access and use of the database. Relevant health practitioners will include those person's authorised by the regulation to use monitored medicines as part of their employment and professional scope of practice.

This new section also authorises for relevant health practitioners to access and use the database for specified purposes. This is intended to limit the access and use of database information to any person or health practitioner that might require such information to guide decisions concerning their treatment or care. This section also provides that the CHO must make the monitored medicines database available to a relevant health practitioner at no cost.

97G Monitored medicines database – access authority

New Section 97G allows for a person to apply to the CHO for an access authority to access and use the monitored medicines database. An access authority must be in writing and include relevant particulars outlined by new subsection 97G(3) of the Act.

This section provides that the CHO may only issue an access authority if considered in the public interest and consistent with the purposes of the monitored medicines database. This new section allows for flexibility in database access should someone other than a relevant health practitioner require access to the database for a public purpose such as ensuring the currency of ICT security or the auditing of database records.

97H Monitored medicines database – offences

Three offences are included within Section 97H addressing potential misuse of the monitored medicines database, and by extension the personal privacy information contained within.

The first offence, set out in Section 97H(1), is the most basic of the offences, addressing unauthorised access of information on the monitored medicines database. For the offence to be proven a prosecution will need to establish that the accused person accessed information on the monitored medicines database and that the access was not authorised by Chapter 6A.

The second offence, set out in Section 97H(2), addresses the unauthorised access and use of information on the monitored medicines database. For the offence to be proven a prosecution will need to establish three components of the offence:

- that the accused person accessed information on the monitored medicines database;
- that the accused used the information that was accessed; and
- that the use of the information accessed was not authorised by Chapter 6A.

The third offence is set out in Section 97H(3), and addresses the unauthorised access and disclosure of information on the monitored medicines database. For the offence to be proven a prosecution will need to establish three components of the offence:

- that the accused person accessed information on the monitored medicines database;
- that the accused disclosed the information that was accessed; and
- that the disclosure of the information accessed was not authorised by Chapter 6A.

The maximum penalty that may be imposed for the offences in subsection 2 and 3 is 50 penalty units. The value of a penalty unit is set out in section 133 of the *Legislation Act 2001*. This maximum penalty set for these offences are similar to those within the *Information Privacy Act 2014*, save for the fact that unlike the *Information Privacy Act 2014* punishment by imprisonment for 6 months cannot be imposed.

The offence in subsection 1 is regarded as less severe than those in subsections 2 and 3, and as such a lower maximum penalty of 30 penalty units has been assigned to this. The unlawful conduct addressed by subsection 1 is the unauthorised access of information on the monitored medicines database only. Accordingly, in these circumstances sensitive privacy information contained on the database has been improperly accessed by the accused person, but the privacy breach is not alleged to have extended beyond the person that accessed the information. That is, the information accessed is not alleged to have then been utilised in some form (which is the focus of the offence in subsection 2) or disclosed (which is the focus of the offence in subsection 3). The unlawful use or disclosure of sensitive privacy information contained on the monitored medicines database is regarded as an aggravating factor warranting a higher maximum penalty.

For each of the three offences, strict liability applies in relation to the first element of the offence; being that the person accessed the information on the monitored medicines database. As strict liability has been applied to this element of the offence, a prosecution will only need to establish beyond a reasonable doubt that the access by the accused person did occur, which is likely to be achieved through access logs for the database. The intention of the accused person when accessing the information does not need to be established by the prosecution due to the application of strict liability to that component. Default fault elements apply to the remaining offence elements.

Clause 6 Disciplinary action against authorisation holders

Section 141 (1) (d)

This provision makes a minor amendment to reflect current drafting practices and preferred language employed by the Parliamentary Counsel's Office.

The amendment replaces the word 'varying' with the term 'amending'. This alteration has no impact on the application or interpretation of the section, and is being done solely for the purpose of legislative drafting consistency.

Clause 7 New section 141 (1) (h)

Section 141 of the Act lists the actions that constitute a 'disciplinary action' when taken against an authorisation holder or previous authorisation holder.

Clause 7 of this Bill inserts a new paragraph (h) into Section 141(1) of the Act to take into account the new monitored medicines database. Through the insertion of paragraph (h) into this section, the CHO may amend, suspend or cancel the authorisation holder's authority to access and use the database.

Such a disciplinary action will most often be appropriate in circumstances in which the authority holder has improperly accessed, used or disclosed information within the monitored medicines database. Disciplinary action in such circumstances may be initiated as an alternative to prosecution of an offence under section 97H proposed by this Bill, or in rare circumstances, in addition to prosecution. The addition of section 141(1)(h) also ensures that the CHO is able to take immediate action in response to unauthorised access, use, or disclosure of private patient information, and to limit any further breaches the Act and of privacy.

Clause 8 Effect of suspension of authorisations

Sections 144 (2) (b) and 145 (1) (b)

This provision makes a minor amendment to reflect current drafting practices and preferred language employed by the Parliamentary Counsel's Office.

The amendment replaces the word 'varied' with the term 'amended'. This alteration has no impact on the application or interpretation of the section, and is being done solely for the purpose of legislative drafting consistency.

Clause 9 Return of certain licences and approvals

Section 145 (1) (c)

This provision makes a minor amendment to reflect current drafting practices and preferred language employed by the Parliamentary Counsel's Office.

The amendment replaces the word 'variation' with the term 'amendment'. This alteration has no impact on the application or interpretation of the section, and is being done solely for the purpose of legislative drafting consistency.

Clause 10 Action by chief health officer in relation to certain licences and approvals

Section 146 (1)

Clause 10 makes a minor amendment to reflect current drafting practices and preferred language employed by the Parliamentary Counsel's Office.

This provision substitutes all of the first subsection in section 146 in order to replace references to 'varied', 'vary' and 'variation' with 'amended', 'amend' and 'amendment', respectively . This alteration has no impact on the application or interpretation of the section, and is being done solely for the purpose of legislative drafting consistency.

Clause 11 Reviewable decisions

Schedule 1, item 6, column 3

This provision makes a minor amendment to reflect current drafting practices and preferred language employed by the Parliamentary Counsel's Office.

The amendment replaces the word 'vary' with the term 'amend'. This alteration has no impact on the application or interpretation of the section, and is being done solely for the purpose of legislative drafting consistency.

Clause 12 Dictionary, new definitions

Clause 12 provides for new definitions to be inserted into the dictionary; being definitions of:

- ‘another jurisdiction’;
- ‘approved data source entity’;
- ‘monitored medicine’;
- ‘monitored medicines database’;
- ‘relevant health practitioner’; and
- ‘required information’.

For the term ‘required information’ as it is to apply to Chapter 6A, the reader is directed to Section 31(4) of the Act. Section 31(4) is a pre-existing provision in the Act which provides that required information, in relation to information to be given to the CHO in relation to the supply of a declared substance is any information prescribed in the Regulation for that purpose. Accordingly, determining what information will be required to be provided to the CHO will require consultation of a relevant provision in the Regulation. Clause 13 of this Bill seeks to amend the Regulation to insert such a provision.

For the term ‘monitored medicine’ as it is to apply in the Act the reader is directed to section 97A. Clause 5 of this Bill seeks to amend the Act to insert Chapter 6A, and within that chapter, section 97A details the definition of ‘monitored medicine’ and that is to have application throughout all of the Act.

For all of the other defined terms listed the reader is directed to an earlier section within Chapter 6A in which the full meaning of the term is explained; section 97B. Clause 5 of this Bill seeks to amend the Act to insert Chapter 6A, and within that chapter, section 97B which details all definitions specific to Chapter 6A.

Part 3 Medicines, Poisons and Therapeutic Goods Regulation 2008

Clause 13 Section 81

Section 31 of the Act contains an offence about failing to give information to the CHO regarding the supply of certain declared substances. That provision, at subsection 31(1)(b) and in subsection 31(4), refers to information required by Regulation that is to be provided to the CHO. Section 81 of the Regulation is the provision that sets out the required information for that purpose.

As Section 31 of the Act is to be modified by this Bill to replace references to ‘controlled medicine’ with the term ‘monitored medicine’, a similar consequential change is needed to Section 81 of the Regulation.

The majority of the alterations to section 81 are purely a consequential change to be in keeping with the introduction of the concept of a 'monitored medicine'. However, in subsection 1(d) the information about the person to whom the medicine is supplied is proposed to now also include the person's date of birth, in addition to the existing requirement of their name and address. The inclusion of the person's date of birth is seen as a necessary extra identifier to ensure accuracy and validity of the information being recorded and relied upon.

Human Rights Considerations

This section provides an overview of the human rights which may be engaged by the Bill and a discussion on reasonable limits. The proposed amendments to the Act have been considered in the context of the objects of the *Human Rights Act 2001* (HRA) and section 28(1) of the HRA which 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.

The right to privacy

Section 12(a) of the HRA provides that a person has the right to not to have his or her privacy, family, home or correspondence interfered with unlawfully or arbitrarily.

The right to privacy is relevant in relation to sections 5 and 13 of the Medicines, Poisons and Therapeutic Goods Amendment Bill 2018 (the Bill) because relevant health practitioners and authorised parties will have access to personal health records. However; the Bill was developed to limit any interference with a person's right to privacy only to circumstances where the interference protects and promotes public health and safety.

The nature of the right affected

The right to privacy is a fundamental right, providing a person with the ability to seek and receive medical treatment while maintaining dignity and freedom from unreasonable interference. The limited scope of the monitored medicines database works to further ensure the extent to the limitation on the right is not beyond what is required. Private health information that is not related to the prescription and supply of a monitored medicine is outside the scope of the monitored medicines database and cannot be included in it. Persons other than a related health professional or person authorised to access the database by the CHO within limited circumstances will not have access to this private health information.

The importance of the purpose of the limitation

The purpose of the monitored medicines database is to promote and protect public health and safety by ensuring information is available to monitor and evaluate the supply of monitored medicines and support the exercise of the CHOs functions. These CHO functions, as outlined in new section 97E, include collecting and storing required information for monitored medicines, entering into arrangements with other jurisdictions or approved data source entities to collect and store information in the monitored medicines database, allowing access, use and disclosure of the monitored medicines database to other jurisdictions, and facilitating public health research.

The limit to the right to privacy occasioned by the establishment of the database and the CHO's powers in relation to the monitored medicines database will be important. If related health professionals are unable to access information regarding a particular patient's existing use of monitored medicines or whether an approval is held by one of the patient's practitioners, they may prescribe a high-risk product and inadvertently increase the risk of misuse, abuse and diversion of scheduled medicines by such patients. This has the potential to cause serious harm or death to the individual patient which affects the entire ACT community and places an increased burden on the health system.

Additionally, the CHO's power to issue an access authority to a person other than a relevant health practitioner allows the CHO to provide information only to persons who will use the information for a purpose of the monitored medicines database and that access is in the public interest. This will ensure that use of the monitored medicines database by people who are not health professionals is limited to purposes that serve the public interest only. This will allow research into the misuse, abuse, and diversion of scheduled medicines by at-risk patients can be undertaken. It is the CHO's responsibility to ensure that any research involving the access, use, or disclosure of content from the monitored medicines database is in the public interest.

The nature and extent of the limitation

The limitation on the right to privacy will only apply to people who have used, or are intending to use, monitored medicines. It is acknowledged that particular patients who are legitimately using monitored medicines, such as those with disability or people treated for chronic conditions, may have their right to privacy limited to a greater extent due to their higher use of these medicines. However; this limitation is appropriate and proportionate to the increased risk associated with the higher use of monitored medicines in such groups.

Both the power to obtain and to disclose the aforementioned information engage the right to privacy in section 12 of the HRA. The right is engaged by the requirement that personal information be provided to a central database, and also by the power to disclose that information in the exercising of the CHO's functions.

The provisions relating to the collection, storage, use, and disclosure of information on the monitored medicines database have been drafted to ensure that any interference with a patient's privacy is not arbitrary. This is because the database serves several legitimate purposes as set out above. In addition, the offence provisions associated with the unauthorised access, use, or disclosure of information on the monitored medicines database serve to protect patient privacy. The application of additional privacy

safeguards contained within the *Health Records (Privacy and Access) Act 1997* and *Information Privacy Act 2014* also function to limit privacy impacts of the Bill through placing obligations on record holders to maintain security and integrity of sensitive information and provides for criminal prosecution if appropriate.

To further limit any undue access or disclosure to private health information, a relevant health practitioner, in remotely accessing the monitored medicines database, is made aware of his or her obligation to protect sensitive information as presented through an online disclaimer. This disclaimer must be acknowledged before any information on the database may be accessed. The ACT Government is also seeking to amend its online forms as appropriate to ensure that patients are made reasonably aware, through their consulting treating health practitioner, that information gathered in relation to their prescription or supply of a monitored medicine may appear on the monitored medicines database, and accessed by relevant health practitioners with responsibility for their care or treatment.

Further, the CHO's powers to collect, store, use and disclose this information can only be exercised for the purposes of establishing and maintaining the database and furthering its purposes. Other jurisdictions, such as Victoria, have similar provisions to ensure the protection of private health information. For this reason, Sections 5 and 13 of the Bill are compatible with Section 12 of the HRA.

Clause 5 of the Bill inserts a new Chapter 6A which allows the CHO to keep a monitored medicines database, in any form, to record information relating to monitored medicines. The monitored medicines database may include information about the supply of a monitored medicine, the approval to prescribe a monitored medicine, information from other jurisdictions in relation to the supply of medicines that are monitored in other jurisdictions, information relating to a monitored medicine from an approved data source, and any other information prescribed by regulation.

In most instances, the information contained in the database will be private health information relating to a specific patient. The information relating to a specific patient can then be accessed by a relevant health practitioner who is treating this patient to inform the prescription of medicines to the patient, their treatment and care, or to disclose the information to the specific patient or another health practitioner in the treatment team.

The information may also be accessed and used by a person who is not a relevant health practitioner only if authorised to do so by the CHO. The CHO must be satisfied that the disclosure of this information will serve a purpose of the monitored medicines database and be in the public interest.

Clause 13 of the Bill amends Regulation 81 of the Medicines, Poisons and Therapeutic Goods Regulation 2008 which defines 'required information' to include the date of birth of the person to whom the medicine is supplied. This is to ensure that data regarding the supply of a monitored medicine can be accurately data-matched to the correct person and that the monitored medicines database can operate effectively.

The relationship between the limitation and its purpose

The purpose of the monitored medicines database is to promote and protect public health and safety by ensuring that information is available to monitor and evaluate the supply of monitored medicines to a person and support the exercise of the CHOs function. The limitation on the right to privacy exists to ensure that misuse, abuse, and diversion of monitored medicines is prevented and public safety is protected. In this instance, public safety is protected by ensuring that health professionals are able to holistically review their patient's access to a monitored medicine before making the decision to prescribe these medicines to a patient. The monitored medicines database is intended to support clinical decision making to promote safe supply, prescription, and dispensing of monitored medicines, and to reduce harm from these medicines.

Additionally, the CHO will be able to issue an access authority to a person other than a relevant health practitioner who has applied for authorisation to access and use the monitored medicines database. To remove doubt, an access authority is intended to include the disclosure of de-identified data, such as statistics, derived from the monitored medicines database. Access authority can only be issued if the CHO is satisfied that providing the access authority to the person is consistent with the purpose of the monitored medicines database under new Section 97C and it is otherwise in the public interest.

Any less restrictive means reasonably available to achieve the purpose the limitation seeks to achieve

The main purpose of the limitation on the right to privacy is to ensure that misuse, abuse and diversion of monitored medicines can be prevented to protect both the person inappropriately using monitored medicines and the broader ACT community. Options to achieve this purpose were considered in the development of the Bill.

Less restrictive means were not deemed appropriate for achieving the purpose of the limitation as relevant health practitioners require a central database of information on the use and supply of monitored medicines to adequately guide appropriate prescription and treatment of the patient in their care. The current lack of a central database has meant that information relating to the prescription and supply of monitored medicines has been kept in isolation. This means that a health practitioner is unable to make treatment decisions based on a patient's actual use of monitored medicines. This has allowed for 'doctor shopping,' where patients seek prescriptions for monitored medicines from multiple prescribers who may not be aware that a patient has already received a prescription for a monitored medicine. Patients were then inappropriately accessing harmful and substantial quantities of monitored medicines.

Further, the Bill has been drafted in such a way as to ensure that only persons who require access to further the purpose of promoting public health and safety are provided access to a particular person's private health information relating to their use of monitored medicines. Specifically, the Bill has been drafted to limit access to the monitored medicines database to persons other than relevant health practitioners to a narrow range of scenarios. For example, limited access may be granted to IT personnel to ensure that ongoing security of the information contained in the database.

The right to the presumption of innocence and the right to fair trial

The offences relating to the access, use and disclosure of information in the monitored medicines database are contained in the new section 97H. The offence elements in Sections 97H(1)(a), 97H(2)(a) and 97H(3)(a) are made strict liability, as the physical elements are conduct and there is no fault element. However; default fault elements of intention or recklessness apply to the remaining offence provisions.

Although these offences engage the presumption of innocence and right to fair trial, strict liability offences are not inherently incompatible with human rights. In the three offences within the proposed section the limitation on the human right in Section 22(1) of the HRA is demonstrably justifiable given community expectations about the conduct to which the offence applies, and the regulated professionals to which the offences could apply. The strict liability elements of the offence are necessary for the operation of the offences; that is, proof of access will be proven through the use of data logs of the monitored medicines database. Importantly, this element of the offence must be strict liability in order to safeguard patient privacy and limit any unauthorised use or disclosure of such information. As strict liability only applies with regard to certain elements of each offence (namely access of the monitored medicines database), the prosecution still has the burden of proof concerning the physical elements of the offence (with regard to access) and both physical and fault elements concerning that the access, use or disclosure of the information was not authorised.

Any person limited by law should be aware, or reasonably aware that they may be subject to such limitations. While there is a strong argument that all registered health professionals ought to be reasonably aware of their obligations to patient privacy due to the operation of the *Health Records (Privacy and Access) Act 1997*, relevant health practitioners are reminded of their obligations to protect sensitive health information, and that penalties may apply to the unauthorised access or use of health information before remote access to the monitored medicines database is granted. This disclaimer must be acknowledged before access to the monitored medicines database is granted to any user. Database access and use is limited to authorised individuals through the use of unique usernames and passwords, and access logs may be audited by ACT Government to ensure appropriate and lawful use.

While the inclusion of strict liability within an offence limits the range of defences that may be available for a person accused of the offence to which it applies, a number of defences remain available to the accused, depending on the particular circumstances of each case. Section 23(1)(b) of the ACT Criminal Code 2002 (the Criminal Code) provides a specific defence to strict liability offences of mistake of fact. Section 23(3) of the Criminal Code provides that other defences may also be available for use for strict liability offences, such as the defence of intervening conduct or event, as provided by Section 39 of the Criminal Code.