Serial 34
Medicines, Poisons and Therapeutic Goods Legislation Amendment Bill 2021
Ms Fyles

A Bill for an Act to amend the *Medicines, Poisons and Therapeutic Goods Act 2012* and the *Medicines, Poisons and Therapeutic Goods Regulations 2014*

NORTHERN TERRITORY OF AUSTRALIA

MEDICINES, POISONS AND THERAPEUTIC GOODS LEGISLATION AMENDMENT ACT 2021

Act No. [ ] of 2021

Table of provisions

NORTHERN TERRITORY OF AUSTRALIA

Act No. [ ] of 2021

An Act to amend the *Medicines, Poisons and Therapeutic Goods Act 2012* and the *Medicines, Poisons and Therapeutic Goods Regulations 2014*

[*Assented to [ ] 2021*]
[*Introduced [ ] 2021*]

The Legislative Assembly of the Northern Territory enacts as follows:

Part 1 Preliminary matters

1 Short title

This Act may be cited as the *Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2021*.

2 Commencement

This Act commences on the day after the day on which the Administrator's assent to this Act is declared.

Part 2 Amendment of Medicines, Poisons and Therapeutic Goods Act 2012

3 Act amended

This Part amends the *Medicines, Poisons and Therapeutic Goods Act 2012*.

4 Section 5 amended (Definitions)

(1) Section 5, definitions ***corresponding law*** and ***eligible midwife***

omit

(2) Section 5

insert

corresponding law:

(a) for section 207 – means a law of a State or another Territory that:

(i) corresponds, or substantially corresponds, to this Act; and

(ii) is declared by regulation to be a corresponding law; or

(b) for Chapter 7, Part 7.1AA – see section 243A.

data source entity, see section 243A.

endorsed midwife, see section 25(6).

monitored medicine, see section 243A.

monitored medicines database, see section 243C(1).

recordable prescription, see section 243B(1) and (2).

recordable supply, see section 243B(3) and (4).

relevant prescriber, see section 243A.

(3) Section 5, definition ***authorised purpose***, paragraph (a)(i)

omit, insert

(i) analysing or testing specimens for the diagnosis of a disease of humans, animals or plants; or

(ia) treatment and prevention of a disease of humans, animals or plants; or

(4) Section 5, definition ***authorised purpose***, paragraph (b)(ii)

omit, insert

(ii) analysing or testing specimens for the diagnosis of a disease of humans or animals; or

(iia) treatment and prevention of a disease of humans or animals; or

(5) Section 5, definition ***authorised purpose***, paragraph (c)(iii)

omit, insert

(iii) analysing or testing specimens for the diagnosis of a disease of humans or animals; or

(iiia) treatment and prevention of a disease of humans or animals; or

5 Section 84 amended (Unrestricted Schedule 8 substance – therapeutic use or treating addiction)

(1) Section 84(2)(b)

omit

substance.

insert

substance;

(2) After section 84(2)(b)

insert

(c) for another purpose prescribed by regulation.

(3) Section 84, at the end

insert

Note for section 84

Section 139(1) provides that the CHO may, on application, authorise the supply, administration or the issue of a prescription for the supply of an unrestricted Schedule 8 substance in a prohibited circumstance.

6 Section 96 amended (Pharmacist to give CHO prescription for supply of Schedule 8 substance)

After section 96(1)

insert

(1A) Subsection (1) does not apply in relation to the supply of a monitored medicine for administration to a person.

Note for subsection (1A)

Section 243E(1)(b) requires information to be given by a pharmacist in relation to the supply of a monitored medicine for administration to a person.

7 Section 207 replaced

Section 207

repeal, insert

207 Offence to disclose certain information

(1) A person commits an offence if:

(a) the person:

(i) obtains information in the course of performing a function connected with the administration of this Act or exercising a power under this Act; or

(ii) is given substance information under an authorisation under section 257(1); and

(b) the information is confidential and the person is reckless in relation to that circumstance; and

(c) the person intentionally engages in conduct; and

(d) the conduct results in the disclosure of the information and the disclosure is not:

(i) for a purpose connected with the administration of this Act, including a legal or disciplinary proceeding arising out of the operation of this Act; or

(ii) to a person who is otherwise entitled to the information; or

(iii) to a person authorised under section 251(1) to be given the information; or

(iv) to a person exercising a power or performing a function under a corresponding law; or

(v) to a health profession body; or

(vi) to a law enforcement agency; or

(vii) in accordance with Chapter 7, Part 7.1AA; and

(e) the person is reckless in relation to the result and circumstance referred to in paragraph (d).

Maximum penalty: 200 penalty units or imprisonment for 2 years.

(2) Strict liability applies to subsection (1)(a).

(3) If the information referred to in subsection (1) relates to a particular person (the ***patient***), it is a defence to a prosecution for an offence against that subsection if the information is disclosed:

(a) with the patient's consent; or

(b) to a health service provider for providing a health service to the patient.

(4) In this section:

health profession body means a National Health Practitioner Board established under the Health Practitioner Regulation National Law.

health service provider, see section 5 of the Health Practitioner Regulation National Law.

law enforcement agency, see section 4 of the *Information Act 2002*.

Note for section 207

In addition to the circumstances mentioned in this section, a person who discloses information mentioned in this section will not be criminally responsible for an offence if the disclosure is justified or excused by or under a law (see section 43BE of the Criminal Code).

8 Chapter 7, Part 7.1AA inserted

After Chapter 7 heading

insert

Part 7.1AA Monitored medicines database

Division 1 Interpretation

243A Definitions

In this Part:

corresponding law means a law of the Commonwealth, a State or another Territory that:

(a) provides for the establishment of a database about monitored medicines; or

(b) is prescribed by regulation to be a corresponding law for this Part.

data source entity means a person or entity approved by the CHO under section 243N.

monitored medicine means:

(a) a Schedule 8 substance; or

(b) any other Scheduled substance prescribed by regulation.

monitored medicines database, see section 243C(1).

recordable prescription, see section 243B(1) and (2).

recordable supply, see section 243B(3) and (4).

relevant prescriber means a dentist, doctor, endorsed midwife, nurse practitioner, podiatrist or another health practitioner prescribed by regulation.

243B Meaning of *recordable prescription* and *recordable supply*

(1) A ***recordable prescription*** is a prescription for a monitored medicine that:

(a) is issued to a person in the Territory; or

(b) is issued outside the Territory to a person who is ordinarily resident in the Territory; or

(c) is issued outside the Territory to a person who has the prescription filled in the Territory; or

(d) is issued in circumstances prescribed by regulation.

(2) Despite subsection (1), a prescription for a monitored medicine that the regulations prescribe to be exempt from a recordable prescription is not a recordable prescription.

(3) A ***recordable supply*** is a supply of a monitored medicine for administration to a person that:

(a) occurs within the Territory; or

(b) occurs outside the Territory if the supply is made to a person ordinarily resident in the Territory; or

(c) occurs outside the Territory if the supply is made on the basis of a prescription issued in the Territory; or

(d) is supplied in circumstances prescribed by regulation.

(4) Despite subsection (3), a supply of a monitored medicine that the regulations prescribe to be exempt from a recordable supply is not a recordable supply.

Division 2 Establishment and maintenance of monitored medicines database

243C Monitored medicines database to be kept

(1) The CHO may establish and keep a database containing information about monitored medicines (the ***monitored medicines database***) to be known by the name prescribed by regulation.

(2) The purposes of the monitored medicines database are as follows:

(a) to promote and protect public health and safety by ensuring that information is available to monitor the supply and sale of monitored medicines to a person;

(b) to reduce harm from monitored medicines;

(c) to facilitate evaluation and research into monitored medicines and the operation of the monitored medicines database.

(3) The monitored medicines database must be kept electronically.

(4) The monitored medicines database may contain any of the following:

(a) records received from a relevant prescriber, pharmacist, data source entity or another person or entity about recordable prescriptions or recordable supplies;

(b) information relating to the issuing of authorities under the Act;

(c) any other information prescribed by regulation.

243D Powers and functions of CHO in relation to database

(1) The CHO may do any of the following in relation to the monitored medicines database:

(a) collect and hold the information specified in section 243C(4) in the database;

(b) access and use the database to:

(i) correct an error or omission in the database; or

(ii) change information held in the database to keep it accurate and up-to-date; or

(iii) facilitate research into public health and the provision of health care; or

(iv) administer, develop and operate the database;

(c) disclose information held in the database:

(i) to the person or entity responsible for keeping an equivalent database to the monitored medicines database under a corresponding law in a State or another Territory, if:

(A) the State or other Territory has a regime for an equivalent database; and

(B) the information only relates to monitored medicines, as defined by the corresponding law in the State or other Territory; and

(C) the information relates to a recordable prescription or recordable supply; or

(ii) for a purpose connected with the administration of this Part, including a legal or disciplinary proceeding arising out of the operation of this Part; or

(iii) to a health profession body; or

(iv) to a law enforcement agency.

(2) The CHO may do any thing or exercise any power reasonably necessary:

(a) to implement, maintain and oversee the monitored medicines database; or

(b) to further the purposes of the database.

(3) The CHO may, by written notice, authorise a person or entity to exercise any of the CHO's powers or perform any of the CHO's functions specified in subsection (1).

(4) An authorisation given under subsection (3) may be subject to any conditions the CHO considers appropriate.

(5) In this section:

health profession body means a National Health Practitioner Board established under the Health Practitioner Regulation National Law.

health service provider, see section 5 of the Health Practitioner Regulation National Law.

law enforcement agency, see section 4 of the *Information Act 2002*.

243E Persons required to give information to CHO

(1) Subject to subsection (2), for the purposes of maintaining the monitored medicines database:

(a) a relevant prescriber must, as soon as practicable after issuing a recordable prescription, give the prescribed information to the CHO in the manner or form the CHO considers appropriate; and

(b) a pharmacist must, as soon as practicable after making a recordable supply, give the prescribed information to the CHO in the manner or form the CHO considers appropriate; and

(c) a data source entity must, as soon as practicable after receiving information from a relevant prescriber or pharmacist about a recordable prescription or recordable supply, give the prescribed information to the CHO in the manner or form the CHO considers appropriate.

(2) In addition, the CHO may require:

(a) the relevant prescriber or pharmacist give the prescribed information specified in subsection (1)(a) or (b) to a data source entity; and

(b) the data source entity give the prescribed information to the CHO in the manner or form the CHO considers appropriate.

(3) The CHO may, by written notice, exempt a specified person from the requirement to give information under subsection (1).

(4) The CHO may, by written notice published on the Agency's website, exempt a specified class of persons from the requirement to give information under subsection (1).

Division 3 Access to monitored medicines database

243F Access for relevant prescribers and pharmacists

(1) The CHO may, on application, authorise a person who is a relevant prescriber or pharmacist to access, use and disclose information held in the monitored medicines database for the following purposes in the performance of the person's duties as a relevant prescriber or pharmacist:

(a) accessing records and information in relation to a person for whom a monitored medicine is intended to be supplied, prescribed or administered;

(b) accessing records and information in relation to a person in relation to the medical treatment or care of that person;

(c) disclosing information in relation to a person to a health practitioner if the relevant prescriber or pharmacist believes, on reasonable grounds, the practitioner intends to supply, prescribe or administer a monitored medicine to the person;

(d) any other purpose prescribed by regulation.

(2) An application for authorisation must be made in the approved form by the person.

(3) The CHO may request further information from the person making the application.

(4) The CHO must consider the application and decide whether to give the authorisation.

(5) The CHO must give the person:

(a) written notice of the CHO's decision; and

(b) if the CHO refuses to give the authorisation – written notice of the reasons for the refusal.

(6) An authorisation given under this section may be subject to any conditions the CHO considers appropriate.

(7) The CHO may revoke an authorisation given under this section at any time by giving the person written notice of the revocation and the reasons for the revocation.

Note for section 243F

A relevant prescriber or pharmacist's access, use or disclosure of the information may be subject to guidelines made under section 243Q.

243G Access for other persons

(1) The CHO may, by written notice published on the Agency's website, authorise a person or class of persons to access, use and disclose information held in the monitored medicines database for the following purposes:

(a) the access, use and disclosure would assist in achieving the purposes of:

(i) promoting safe supply, prescription and dispensing practices; and

(ii) reducing harm from monitored medicines;

(b) the access, use and disclosure is for technical or administrative purposes relating to the maintenance of the database;

(c) the access, use and disclosure is to facilitate evaluation and research into monitored medicines and the operation of the monitored medicines database.

(2) Before giving an authorisation under subsection (1), the CHO must be satisfied that the person or class of persons has appropriate arrangements for:

(a) the security of the information; and

(b) when the person or class of persons no longer requires the information – the destruction or disposal of the information.

(3) An authorisation given under subsection (1) may be subject to any conditions the CHO considers appropriate.

(4) The CHO may revoke an authorisation given under subsection (1) at any time.

Note for section 243G

A person's access, use or disclosure of the information may be subject to guidelines made under section 243Q.

Division 4 Offences

243H Person must not contravene requirement to give information

(1) A person commits an offence if:

(a) the person is required, under section 243E, to give information to the CHO in the manner or form the CHO considers appropriate; and

(b) the person contravenes the requirement.

Maximum penalty: 50 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

(3) It is a defence to a prosecution for an offence against subsection (1) if the person has a reasonable excuse.

243J Relevant prescriber must check database before prescribing monitored medicine

(1) A relevant prescriber commits an offence if:

(a) the relevant prescriber issues a prescription for a monitored medicine to another person; and

(b) the relevant prescriber does not check the information held in the monitored medicines database in relation to the other person before issuing the prescription; and

(c) the prescription is not issued in circumstances that are prescribed by regulation to be exempt.

Maximum penalty: 50 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

(3) It is a defence to a prosecution for an offence against subsection (1) if the relevant prescriber has a reasonable excuse.

243K Pharmacist must check database before supplying monitored medicine

(1) A pharmacist commits an offence if:

(a) the pharmacist supplies a monitored medicine to another person; and

(b) the pharmacist does not check the information held in the monitored medicines database in relation to the other person before supplying the monitored medicine; and

(c) the supply is not made in circumstances that are prescribed by regulation to be exempt.

Maximum penalty: 50 penalty units.

(2) An offence against subsection (1) is an offence of strict liability.

(3) It is a defence to a prosecution for an offence against subsection (1) if the pharmacist has a reasonable excuse.

243L Unauthorised access, use or disclosure of information

(1) A person commits an offence if:

(a) the person is not authorised by or under this Act to access information held in the monitored medicines database; and

(b) the person intentionally accesses information held in the monitored medicines database.

Maximum penalty: 200 penalty units or imprisonment for 2 years.

(2) A person commits an offence if:

(a) the person is not authorised by or under this Act to use information held in the monitored medicines database; and

(b) the person intentionally uses information held in the monitored medicines database.

Maximum penalty: 200 penalty units or imprisonment for 2 years.

(3) A person commits an offence if:

(a) the person is not authorised by or under this Act to disclose information held in the monitored medicines database; and

(b) the person intentionally discloses information held in the monitored medicines database.

Maximum penalty: 200 penalty units or imprisonment for 2 years.

(4) A person commits an offence if:

(a) the person is authorised by or under this Act to access, use or disclose information held in the monitored medicines database; and

(b) the person intentionally accesses, uses or discloses information held in the database; and

(c) the access, use or disclosure results in the contravention of the authorisation or any conditions of the authorisation and the person is reckless in relation to that result.

Maximum penalty: 200 penalty units or imprisonment for 2 years.

(5) Strict liability applies to subsections (1)(a), (2)(a), (3)(a) and (4)(a).

(6) It is a defence to a prosecution for an offence against subsection (4) if the person has a reasonable excuse.

Division 5 Administrative matters

243M Protection from liability for duties and functions in relation to database

(1) A relevant prescriber, pharmacist or person authorised under section 243G(1) is not liable for anything done in good faith in carrying out any duty in relation to, or in accessing, using or disclosing information held in, the monitored medicines database in accordance with this Act or the Regulations.

(2) Without limiting subsection (1):

(a) the accessing of information held in the monitored medicines database in respect of a person or the giving of information to the database in respect of a person does not constitute unprofessional conduct or a breach of professional etiquette or ethics; and

(b) no liability for defamation is incurred by a person mentioned in subsection (1) because of the accessing of any person's information or the provision of that information.

243N Data source entity

The CHO may, by written notice published on the Agency's website, approve a person or entity to be a data source entity.

243P Sharing agreement

The CHO may enter into an agreement or arrangement with the Commonwealth, a State or another Territory or an entity for the sharing of the information held in the monitored medicines database and any equivalent database maintained in a State or another Territory under a corresponding law.

243Q Guidelines

(1) The CHO may make guidelines in relation to the access, use and disclosure of information held in the monitored medicines database under this Part.

(2) The guidelines must be published on the Agency's website.

9 Part 9.4 inserted

After section 295

insert

Part 9.4 Transitional matters for Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2021

296 Definitions

In this Part:

amending Act means the *Medicines, Poisons and Therapeutic Goods Legislation Amendment Act 2021*.

commencement means the day on which section 8 of the amending Act commences.

297 Information obtained before commencement

(1) This section applies in relation to information obtained under section 96 or 139 before the commencement that, if obtained after the commencement, would be information required to be given to the CHO under Chapter 7, Part 7.1AA.

(2) The information is taken to be information obtained under Chapter 7, Part 7.1AA after the commencement.

298 Offences – before and after commencement

(1) Section 207, as inserted by the amending Act, applies only in relation to an offence committed after the commencement.

(2) Section 207, as in force before the commencement, continues to apply in relation to an offence committed before the commencement.

(3) For this section, if any of the conduct constituting an offence occurred before the commencement, the offence is taken to have been committed before the commencement.

10 Schedule 2 amended (Original decisions and affected persons)

Schedule 2, at the end

insert

Refusing to give authorisation (section 243F(5))	Person who receives notice
Revocation of authorisation (section 243F(7))	Person who receives notice

11 Act further amended

The Schedule has effect.

Part 3 Amendment of Medicines, Poisons and Therapeutic Goods Regulations 2014

12 Regulations amended

This Part amends the *Medicines, Poisons and Therapeutic Goods Regulations 2014*.

13 Regulation 3 amended (Definitions)

Regulation 3

insert

custodial correctional facility, for Part 6A, see regulation 81B.

prisoner, for Part 6A, see regulation 81B.

14 Regulation 5 amended (Corresponding law)

(1) Regulation 5

omit

paragraph (b) of the definition ***corresponding law*** in section 5 of the Act,

insert

section 5 of the Act, definition ***corresponding law***, paragraph (a)(ii),

(2) Regulation 5(c)

omit, insert

(c) *Medicines and Poisons Act 2019* (Qld);

(3) Regulation 5(e)

omit, insert

(e) *Medicines and Poisons Act 2014* (WA);

15 Regulations 7A and 7B inserted

After regulation 7

insert

7A Prescribed conditions

For section 58(2)(a) of the Act, the following conditions are prescribed:

(a) for a Schedule 8 substance that is an unrestricted Schedule 8 substance – the pharmacist must verify:

(i) the identity of the person presenting the prescription; and

(ii) the validity of the prescription;

(b) for an amphetamine or methylphenidate prescribed by an interstate prescriber who would otherwise ordinarily be endorsed to initiate treatment in the Territory – the pharmacist must verify:

(i) the identity of the person presenting the prescription; and

(ii) the validity of the prescription; and

(iii) the specialty of the interstate prescriber.

Example for paragraphs (a)(i) and (b)(i)

The pharmacist may request proof of the person's identity.

Example for paragraphs (a)(ii) and (b)(ii)

The pharmacist may contact the prescriber to ascertain the validity of the prescription.

7B Prohibited circumstance

For section 84(2)(c) of the Act, issuing a prescription for the supply of an unrestricted Schedule 8 substance to a person for therapeutic use if the person's daily total oral morphine equivalent dose would be equal to or exceed 100 mg daily is prohibited.

Note for regulation 7B

Section 139(1) of the Act provides that the CHO may, on application, authorise the supply, administration or the issue of a prescription for the supply of an unrestricted Schedule 8 substance in a prohibited circumstance.

16 Part 6A inserted

After regulation 81A

insert

Part 6A Monitored medicines database

81B Definitions

In this Part:

custodial correctional facility, see section 11(1)(a) of the *Correctional Services Act 2014*.

prisoner, see section 6 of the *Correctional Services Act 2014*.

81C Monitored medicine

For section 243A of the Act, definition ***monitored medicine***, paragraph (b), the following Scheduled substances are prescribed:

(a) each benzodiazepine that is a Schedule 4 substance;

(b) codeine;

(c) gabapentin;

(d) pregabalin;

(e) quetiapine;

(f) tramadol;

(g) zolpidem;

(h) zopiclone.

81D Database name

For section 243C(1) of the Act, the name NTScript is prescribed.

81E Information to be given to CHO

(1) For section 243E(1)(a) of the Act, the prescribed information in relation to a recordable prescription is as follows:

(a) the date the prescription was issued;

(b) the name and address of the person to whom the prescription was issued;

(c) the date of birth of the person to whom the prescription was issued;

(d) the name, form, strength and quantity of the monitored medicine prescribed;

(e) the number of repeats permitted under the prescription;

(f) the directions for use of the monitored medicine;

(g) the name, address and phone number of the person who issued the prescription.

(2) For section 243E(1)(b) of the Act, the prescribed information in relation to a recordable supply is as follows:

(a) the date of the supply;

(b) the name and address of the person to whom the supply was made;

(c) the date of birth of the person to whom the supply was made;

(d) the name, form, strength and quantity of the monitored medicine supplied;

(e) the directions for use of the monitored medicine supplied;

(f) the name, address and phone number of the person who authorised the supply;

(g) the name, address and phone number of the pharmacy or pharmacy department from which the supply was made.

(3) For section 243E(1)(c) of the Act, the prescribed information:

(a) in relation to a recordable prescription – is the information specified in subregulation (1); and

(b) in relation to a recordable supply – is the information specified in subregulation (2).

81F Prescription issued by relevant prescriber in exempt circumstances

For section 243J(1)(c) of the Act, the following circumstances are exempt:

(a) a relevant prescriber issues a prescription for a monitored medicine to a person who is being treated in an aged care facility;

(b) a relevant prescriber issues a prescription for a monitored medicine to a person who is a prisoner in a custodial correctional facility;

(c) a relevant prescriber issues a prescription for a monitored medicine to a person who is suffering a life threatening illness and the supply of the monitored medicine is intended to provide palliative treatment in an end of life situation.

81G Supply made by pharmacist in exempt circumstances

For section 243K(1)(c) of the Act, the following circumstances are exempt:

(a) a pharmacist supplies a monitored medicine to a person who is being treated in an aged care facility;

(b) a pharmacist supplies a monitored medicine to a person who is a prisoner in a custodial correctional facility;

(c) a pharmacist supplies a monitored medicine to a person who is suffering a life threatening illness and the supply of the monitored medicine is intended to provide palliative treatment in an end of life situation.

17 Schedule 1 replaced

Schedule 1

repeal, insert

Schedule 1 Infringement notice offences and prescribed amounts

regulation 82

Provision	Prescribed amount in penalty units	
	for individual	for body corporate
Medicines, Poisons and Therapeutic Goods Act 2012		
sections 97(2) and (3), 107(1) and 176(1) and (2)	1	
section 243H(1)	2	10
sections 243J(1) and 243K(1)	2	
Medicines, Poisons and Therapeutic Goods Regulations 2014		
regulations 31(1), 62(1) and 77(1)	3	
regulations 19(1), 28(1), 29(1), 30(1), 67(1), 68(1) and 69(1)	2	
regulations 27(1), 63(1), 65(1), 66(1), 70(1), 71(1) and 72(1)	1	

Part 4 Repeal of Act

18 Repeal of Act

This Act is repealed on the day after it commences.

Schedule Act further amended

section 11

Provision	Amendment	
	omit	*insert*
section 25(6)	***eligible***	***endorsed***
section 57(2)(a), 81(1)(a)(i) and 83(1)(a)(i)	eligible	endorsed