



New South Wales

# Poisons and Therapeutic Goods Amendment (Voluntary Assisted Dying Substances) Regulation 2023

under the

Poisons and Therapeutic Goods Act 1966

His Excellency the Lieutenant-Governor, with the advice of the Executive Council, has made the following regulation under the *Poisons and Therapeutic Goods Act 1966*.

RYAN PARK, MP  
Minister for Health

## Explanatory note

The objects of this regulation are—

- (a) to make provision for the handling of substances prescribed for purposes under the *Voluntary Assisted Dying Act 2022*, including the following—
  - (i) the form and retention of prescriptions,
  - (ii) storage,
  - (iii) keeping of records,
  - (iv) delivery, and
- (b) to make provision for drugs of addiction to be destroyed by retail pharmacists with appropriate supervision and record keeping, and
- (c) to clarify the circumstances in which a person has lawful authority to access information on the database kept under the *Poisons and Therapeutic Goods Regulation 2008*, Part 8A.

## **Poisons and Therapeutic Goods Amendment (Voluntary Assisted Dying Substances) Regulation 2023**

under the

Poisons and Therapeutic Goods Act 1966

### **1 Name of regulation**

This regulation is the *Poisons and Therapeutic Goods Amendment (Voluntary Assisted Dying Substances) Regulation 2023*.

### **2 Commencement**

This regulation commences as follows—

- (a) for Schedule 1[1]–[3] and [6]—on 28 November 2023,
- (b) otherwise—on the day on which it is published on the NSW legislation website.

## Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

### [1] Clause 3 Definitions

Insert in alphabetical order in clause 3(1)—

*administering practitioner*, for Part 4A—see clause 128B.

*authorised disposer*, for Part 4A—see clause 128B.

*authorised supplier*, for Part 4A—see clause 128B.

*contact person*, for Part 4A—see clause 128B.

*coordinating practitioner*, for Part 4A—see clause 128B.

*patient*, for Part 4A—see clause 128B.

*voluntary assisted dying substance* has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**Note—** See the *Voluntary Assisted Dying Act 2022*, section 7, which provides for the approval of a Schedule 4 or 8 substance as a voluntary assisted dying substance.

### [2] Part 3, Division 1A

Insert before Division 1—

#### Division 1A Preliminary

##### 25A Application of part

This part, other than clauses 61 and 67, does not apply to—

- (a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, or
- (b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

### [3] Part 4, Division 1A

Insert before Division 1—

#### Division 1A Preliminary

##### 68J Application of part

This part, other than Division 5 and clause 124, does not apply to—

- (a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, or
- (b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

### [4] Clause 125 Drugs of addiction not to be destroyed

Insert “125A,” after “clause” in clause 125(2)(d).

### [5] Clause 125A

Insert after clause 125—

#### 125A Destruction of drugs of addiction by retail pharmacists

- (1) A pharmacist who practises at a retail pharmacy may destroy a drug of addiction at the pharmacy in the presence of an independent witness.

- (2) A pharmacist who destroys a drug of addiction must ensure the following are recorded in the drug register kept at the pharmacy—
- (a) the date of destruction,
  - (b) the name and quantity of the drug destroyed,
  - (c) the pharmacist’s name, registration number and signature,
  - (d) the independent witness’s name, registration number and signature.
- (3) In this clause—
- family member** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.
- independent witness** means a medical practitioner, nurse practitioner or pharmacist who—
- (a) is not employed or otherwise engaged to provide professional services at the pharmacy, and
  - (b) is not a family member of the pharmacist, and
  - (c) if the independent witness is a pharmacist—does not have a financial interest, within the meaning of the *Health Practitioner Regulation National Law (NSW)*, Schedule 5F, in the pharmacy.

[6] **Part 4A**

Insert after clause 128A—

## **Part 4A Voluntary assisted dying substances**

**Note—** See also the *Voluntary Assisted Dying Act 2022* and this regulation, clauses 61, 67 and 124 and Part 4, Division 5.

### **Division 1 Preliminary**

#### **128B Definitions**

In this part—

**administering practitioner** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**authorised disposer** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**authorised supplier** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**contact person**, for a patient, has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**coordinating practitioner** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**patient** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

#### **128C Application of part**

This part applies to—

- (a) a prescription for a voluntary assisted dying substance for use under the *Voluntary Assisted Dying Act 2022*, and
- (b) a voluntary assisted dying substance prescribed in accordance with the *Voluntary Assisted Dying Act 2022*.

## Division 2 Storage

### 128D Storage by authorised supplier

- (1) An authorised supplier who has possession of a voluntary assisted dying substance that is a restricted substance must keep the substance—
- (a) in a room or enclosure to which the public does not have access, and
  - (b) apart from food intended for consumption by humans or animals, and
  - (c) in such a way that, if its container breaks or leaks, the substance cannot mix with or contaminate food intended for consumption by humans or animals.

Maximum penalty—20 penalty units.

- (2) An authorised supplier who has possession of a voluntary assisted dying substance that is a drug of addiction must keep the substance in a safe that is—
- (a) securely attached to a part of the premises, and
  - (b) securely locked when not in immediate use, and
  - (c) not used to store anything other than drugs of addiction or restricted substances.

Maximum penalty—20 penalty units.

- (3) An authorised supplier must ensure—
- (a) for a safe that is unlocked by a key or other device—the key or device is kept safely and securely, and
  - (b) for a safe that is unlocked by a code or combination—the code or combination is not revealed to an unauthorised person.

Maximum penalty—20 penalty units.

### 128E Storage at health care establishments and residential facilities

- (1) If a voluntary assisted dying substance is kept at a health care establishment or residential facility on behalf of a patient, the substance must be stored in the steel box required by the *Voluntary Assisted Dying Act 2022*, section 79 and the box must be kept—
- (a) in a storage room that is securely locked when not in immediate use, or
  - (b) in a safe, cupboard or other receptacle that is—
    - (i) securely attached to the establishment or facility, and
    - (ii) securely locked when not in immediate use.

**Note—** See also the *Voluntary Assisted Dying Act 2022*, section 89(2)(d), which provides that a health care establishment or residential facility may refuse to store a voluntary assisted dying substance.

- (2) In this clause—

**health care establishment** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

**residential facility** has the same meaning as in the *Voluntary Assisted Dying Act 2022*.

### 128F Means to unlock storage box to be kept securely

A person who receives a voluntary assisted dying substance must ensure—

- (a) if the steel box in which the substance is required to be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a key or other device—the key or device is kept safely and securely, and

- (b) if the steel box in which the substance is required to be stored by the *Voluntary Assisted Dying Act 2022*, section 79 is unlocked by a code or combination—the code or combination is not revealed to an unauthorised person.

Maximum penalty—20 penalty units.

### **Division 3 Records**

**Note—** See clause 176 regarding the keeping of records.

#### **128G Prescriptions to be kept**

- (1) A coordinating practitioner who prescribes a voluntary assisted dying substance must keep a copy of the prescription for the substance.  
Maximum penalty—20 penalty units.
- (2) An authorised supplier who supplies a voluntary assisted dying substance must keep the prescription or a copy of the prescription for the substance.  
Maximum penalty—20 penalty units.

#### **128H Records to be kept by authorised supplier**

- (1) An authorised supplier must, in accordance with this clause, keep written records of voluntary assisted dying substances supplied by the authorised supplier.  
Maximum penalty—20 penalty units.
- (2) A record of the supply of a voluntary assisted dying substance must be made as soon as practicable after the substance is supplied and include the following—
  - (a) the name of the substance,
  - (b) the name and address of the patient for whom the substance was prescribed,
  - (c) the quantity supplied,
  - (d) the name of the person to whom the substance was supplied,
  - (e) the name of the coordinating practitioner who prescribed the substance,
  - (f) the address of the premises at which the substance was supplied,
  - (g) the date the substance was supplied and the record made,
  - (h) the name and signature of the person making the record.

**Note—** A record kept under this clause may be kept in a drug register.

#### **128I Records to be kept by administering practitioner**

- (1) An administering practitioner must, in accordance with this clause, keep written records of voluntary assisted dying substances received, administered and disposed of by the administering practitioner.  
Maximum penalty—20 penalty units.
- (2) A record of the receipt of a voluntary assisted dying substance must be made on the day the substance is received and include the following—
  - (a) the name of the substance,
  - (b) the quantity received,
  - (c) the name and address of the person from whom the substance was received,

- (d) the name of the patient for whom the substance was prescribed,
  - (e) the date the substance was received and the record made,
  - (f) the name and signature of the person making the record.
- (3) A record of the administration of a voluntary assisted dying substance must be made on the day the substance is administered and include the following—
- (a) the name of the substance,
  - (b) the quantity administered,
  - (c) the name of the patient to whom the substance was administered,
  - (d) the date the substance was administered and the record made,
  - (e) the address of the premises at which the substance was administered,
  - (f) the name and signature of the person making the record.
- (4) A record of the disposal of a voluntary assisted dying substance must be made on the day the substance is disposed of and include the following—
- (a) the name of the substance,
  - (b) the quantity disposed of,
  - (c) the means of disposal,
  - (d) if the substance is disposed of by destruction in accordance with clause 128LA(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,
  - (e) the date the substance was disposed of and the record made,
  - (f) the name and signature of the person making the record.

**Note—** A record kept under this clause may be kept in a drug register.

#### **128J Records to be kept by authorised disposer**

- (1) An authorised disposer must, in accordance with this clause, keep written records of voluntary assisted dying substances received for disposal and disposed of by the authorised disposer.  
Maximum penalty—20 penalty units.
- (2) A record of the receipt of a voluntary assisted dying substance must be made on the day the substance is received and include the following—
- (a) the name of the substance,
  - (b) the quantity received,
  - (c) the name and address of the person from whom the substance was received,
  - (d) the name and address of the patient for whom the substance was prescribed,
  - (e) the date the substance was received for disposal and the record made,
  - (f) the name and signature of the person making the record.
- (3) A record of the disposal of a voluntary assisted dying substance must be made on the day the substance is disposed of and include the following—
- (a) the name of the substance,
  - (b) the quantity disposed of,
  - (c) the means of disposal,

- (d) if the substance is disposed of by destruction in accordance with clause 128LA(2)—the name, registration number and signature of the relevant practitioner in whose presence the substance was destroyed,
- (e) the date the substance was disposed of and the record made,
- (f) the name and signature of the person making the record.

**Note—** A record kept under this clause may be kept in a drug register.

**128K Records may be kept electronically**

A record under this division may be kept electronically.

**Division 4 Miscellaneous**

**128L Form and use of prescription**

- (1) A prescription for a voluntary assisted dying substance to be used for a purpose under the *Voluntary Assisted Dying Act 2022* must include—
  - (a) the date on which the prescription is issued, and
  - (b) the following details for the patient—
    - (i) name,
    - (ii) date of birth,
    - (iii) address,
    - (iv) identification number, and
  - (c) the name, strength and quantity of the voluntary assisted dying substance to be supplied, and
  - (d) adequate directions for use of the voluntary assisted dying substance, and
  - (e) the following details for the coordinating practitioner who issued the prescription—
    - (i) name,
    - (ii) telephone number,
    - (iii) practice address,
    - (iv) identification number, and
  - (f) the coordinating practitioner’s signature.

Maximum penalty—20 penalty units.

**Note—** See also the *Voluntary Assisted Dying Act 2022*, section 74, which sets out certain mandatory matters for a prescription for a voluntary assisted dying substance.

- (2) Despite another provision of this regulation, if other substances are prescribed for a patient to assist in the administration of the voluntary assisted dying substance, the same prescription may be used for—
  - (a) the voluntary assisted dying substance, and
  - (b) the other substances.
- (3) In this clause—

**identification number** means—

  - (a) for a coordinating practitioner—the identification number given to the practitioner by the Voluntary Assisted Dying Board, or
  - (b) for a patient—the identification number given to the patient by the Voluntary Assisted Dying Board.



***Voluntary Assisted Dying Board*** means the Voluntary Assisted Dying Board established by the *Voluntary Assisted Dying Act 2022*, section 134.

**128LA Disposal**

- (1) An authorised disposer or administering practitioner must not dispose of a voluntary assisted dying substance in a place or in a way likely to constitute a risk to the public.  
Maximum penalty—20 penalty units.
- (2) An authorised disposer or administering practitioner who destroys a voluntary assisted dying substance must do so in the presence of a relevant practitioner.  
Maximum penalty—20 penalty units.
- (3) In this clause—  
***relevant practitioner*** means the following—
  - (a) a medical practitioner,
  - (b) a pharmacist,
  - (c) a registered nurse.

**Note**— See also the *Voluntary Assisted Dying Act 2022*, sections 80–83, which concern the disposal of voluntary assisted dying substances, including the recording and notifying of disposal.

**128LB Mode of delivery—authorised supplier**

- (1) An authorised supplier who supplies a voluntary assisted dying substance must deliver the substance—
  - (a) personally, or
  - (b) by carrier.Maximum penalty—20 penalty units.
- (2) An authorised supplier who delivers a voluntary assisted dying substance personally must obtain a signed and dated receipt from the person to whom the substance is supplied.  
Maximum penalty—20 penalty units.
- (3) An authorised supplier who delivers a voluntary assisted dying substance by carrier must—
  - (a) obtain and keep written evidence of the consignment of the substance, and
  - (b) ensure the carrier—
    - (i) obtains a signed and dated receipt from the person to whom the substance is delivered, and
    - (ii) gives the receipt to the authorised supplier.Maximum penalty—20 penalty units.

**128LC Mode of delivery—contact person**

- (1) A contact person who gives a voluntary assisted dying substance to an authorised disposer must deliver the substance—
  - (a) personally, or
  - (b) by carrier.Maximum penalty—20 penalty units.

- (2) A contact person who delivers a voluntary assisted dying substance to an authorised disposer by carrier must—
- (a) obtain and keep written evidence of the consignment of the substance, and
  - (b) ensure the carrier—
    - (i) obtains a dated and signed receipt from the person to whom the substance is delivered, and
    - (ii) gives the receipt to the contact person.
- Maximum penalty—20 penalty units.

**128LD Delivery by carrier**

- (1) A carrier is authorised to be in possession of a package containing a voluntary assisted dying substance only for the purpose of delivering the substance to the person to whom it is addressed.
- (2) An authorised supplier who delivers a voluntary assisted dying substance by carrier must ensure—
- (a) the substance is contained in a package that has at least 1 opaque covering, and
  - (b) the package contains a document—
    - (i) listing the contents of the package, and
    - (ii) bearing the words “VOLUNTARY ASSISTED DYING SUBSTANCE—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5mm, and
  - (c) the outside of the package does not indicate that it contains a voluntary assisted dying substance, a drug of addiction or a restricted substance, and
  - (d) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—20 penalty units.

- (3) A contact person who delivers a voluntary assisted dying substance by carrier must ensure—
- (a) the substance is contained in a package that has at least 1 opaque covering, and
  - (b) the outside of the package does not indicate that it contains a voluntary assisted dying substance, a drug of addiction or a restricted substance, and
  - (c) the package is properly addressed to the person to whom the substance is being supplied.

Maximum penalty—20 penalty units.

**[7] Clause 174I Unauthorised access to database**

Omit clause 174I(2). Insert instead—

- (2) For this clause, *lawful authority* includes the person acting—
- (a) under the direction of a dentist, medical practitioner or nurse practitioner, and
  - (b) for a purpose under clause 174H(1) or (2).