Voluntary Assisted Dying Regulation 2022

Explanatory notes for SL 2022 No. 118

made under the

Voluntary Assisted Dying Act 2021

General Outline

Short title

Voluntary Assisted Dying Regulation 2022

Authorising law

Section 167 of the *Voluntary Assisted Dying Act 2021*

Policy objectives and the reasons for them

The *Voluntary Assisted Dying Act 2021* (the Act) was passed by the Legislative Assembly on 16 September 2021 and received Royal Assent on 23 September 2021. The voluntary assisted dying scheme (the scheme) commences on 1 January 2023. To allow the Voluntary Assisted Dying Review Board (the Review Board) to be established before commencement of the scheme, part 8 and section 153 of the Act commenced six months after assent. The *Voluntary Assisted Dying Regulation 2022* (the Regulation), which supports the effective operation of the Act, will commence with the Act on 1 January 2023.

The Act will provide individuals who are suffering and dying with an additional end-of-life choice, allowing eligible people to choose the timing and circumstances of their death. Voluntary assisted dying involves the administration of a substance to cause a person's death. The Act defines a voluntary assisted dying substance to mean a substance approved by the chief executive under section 160 of the Act.

The Queensland scheme was established by the Act and based on the recommendations of the Queensland Law Reform Commission (QLRC) report: *A legal framework for voluntary assisted dying* (Report No. 79) (QLRC report) and draft QLRC legislation. The QLRC aimed to develop a draft law for Queensland that is compassionate, safe and practical.

The framework for how the voluntary assisted dying substance will be managed is established under division 3, part 4 of the Act. In addition to the general regulation-making head of power, the Act provides that the following technical matters relating to the management of the voluntary assisted dying substance may be prescribed by regulation:

- prescribing a voluntary assisted dying substance (section 67 of the Act);

- labelling a voluntary assisted dying substance (section 71 of the Act);
- supplying a voluntary assisted dying substance (section 73 of the Act);
- storage of a voluntary assisted dying substance (section 74 of the Act); and
- disposal of a voluntary assisted dying substance (section 79 of the Act).

The Act also provides for the functions of the Review Board, which includes recording and keeping information prescribed by regulation about requests for, and provision of, voluntary assisted dying (section 117 of the Act).

Prescribing

Section 66 of the Act sets out the requirements for a coordinating practitioner when prescribing a voluntary assisted dying substance, such as including a statement that indicates that it is for a voluntary assisted dying substance, details of the substance and the person's name and telephone number. These requirements implement the QLRC's report recommendation, which is designed to add further rigour to the prescribing process and ensure that the prescription can be easily identified as being for a voluntary assisted dying substance (paragraph 11.59).

Section 67 of the Act provides that a regulation may prescribe other requirements a coordinating practitioner must comply with when prescribing a voluntary assisted dying substance.

Labelling

Section 71 of the Act provides that an authorised supplier who supplies a voluntary assisted dying substance must comply with labelling requirements prescribed by regulation.

The QLRC report states it is important to be able to readily identify a voluntary assisted dying substance, given its nature, and the requirements prescribed by regulation should include that the authorised supplier must attach a statement to the package or container warning of the purpose of the substance, the dangers of administration, storage and disposal requirements (paragraph 11.98).

Supply

Sections 69 of the Act provides that the authorised supplier who is given a prescription for a voluntary assisted dying substance must not supply the substance in accordance with the prescription unless they have confirmed the authenticity of the prescription, the identity of the person who issued the prescription and the identity of the person to whom the substance is to be supplied.

The QLRC report states that authorised suppliers will act as an essential check and balance on the process (paragraph 11.95).

Section 158 of the Act provides that the chief executive of Queensland Health may authorise an appropriately qualified registered health practitioner, or person in a class of registered health practitioners, to be an authorised supplier for the purpose of supplying a voluntary assisted dying substance under the Act. Pharmacists employed within the Queensland Voluntary

Assisted Dying Pharmacy (QVAD-Pharmacy) will be authorised as authorised suppliers to supply the voluntary assisted dying substance.

Section 70 of the Act sets out a requirement for the authorised supplier to provide particular information when supplying the voluntary assisted dying substance. This requirement applies if an authorised supplier supplies a voluntary assisted dying substance to a person, the contact person for a person or an agent of a person after a self-administration decision.

Section 72 of the Act requires an authorised supplier who supplies a voluntary assisted dying substance complete a record of the supply in the approved form (the authorised supply form).

The QLRC report states that this requirement will support the safe management of the substance by ensuring all instances of supply are recorded and assists the Review Board in its monitoring and review role (paragraph 11.99).

Section 73 of the Act provides that a regulation may prescribe other requirements with which an authorised supplier must comply in relation to supplying a voluntary assisted dying substance. This will enable any technical or prescriptive matters to be dealt with by regulation.

The QLRC report states that authorised suppliers will act as an essential check and balance on the process (paragraph 11.95). The QLRC report recommended further requirements relating to supply of the voluntary assisted dying substance be prescribed by regulation (recommendation 11-3(f)).

Storage

Sections 52 and 53 of the Act provide the authorisations for the prescription, supply and administration of the voluntary assisted dying substance that apply if a person makes a self-administration or practitioner administration decision. Section 61 of the Act sets out the role of the contact person and authorises the contact person to receive, possess, supply the substance to the person and give the substance to an authorised disposer.

The authorisations were included in the Act to support a person to safely administer the voluntary assisted dying substance. The purpose of the authorisations is to provide clarity on what a person is authorised to do with the voluntary assisted dying substance once it leaves the control of an authorised supplier (paragraph 11.121 of the QLRC Report).

Section 65 of the Act requires the coordinating practitioner for an eligible person who has made a self-administration decision, before prescribing a voluntary assisted dying substance for the person, to provide written information on how the substance must be stored in accordance with the requirements prescribed by regulation.

Similarly, section 70 of the Act requires the authorised supplier who supplies a voluntary assisted dying substance to the person, the contact person or an agent of the person that has made a self-administration decision, must provide written information to the recipient about the storage requirements for the substance as prescribed by regulation.

The QLRC report states that to ensure the voluntary assisted dying substance is managed safely once it has left the control of the authorised supplier, the person who receives the substance must store it in accordance with the requirements prescribed by regulation. The Report also

provides that the storage requirements should include that the person must keep the substance in a locked box not easily penetrable by other people (paragraphs 11.123 and 11.125).

Section 74 of the Act provides that a person who receives a voluntary assisted dying substance must store the substance in accordance with the requirements prescribed by regulation.

Disposal

Sections 75 to 78 of the Act regulate the disposal of a voluntary assisted dying substance.

Section 75 of the Act allows an authorised disposer to receive a voluntary assisted dying substance, or any unused or remaining substance from the contact person. The Act also allows the authorised disposer to possess the substance for the purpose of disposing it and to dispose of the substance. The authorised disposer must dispose of the substance, or unused or remaining substance, as soon as practicable after receiving it.

The QLRC report considers this necessary to ensure the voluntary assisted dying substance is managed appropriately while in the community (paragraph 11.166).

Similarly, section 77 of the Act applies if a person has made a practitioner administration decision and revokes the decision or dies. In this case, if the administering practitioner has possession of the voluntary assisted dying substance, or any unused or remaining substance, then the administering practitioner is authorised to dispose of the voluntary assisted dying substance.

Section 79 of the Act provides that a regulation may prescribe other requirements with which an authorised disposer or administering practitioner must comply in relation to disposing of a voluntary assisted dying substance or unused or remaining substance. This enables technical or prescriptive matters to be dealt with by regulation.

The Act provides that an authorised disposer is a registered health practitioner authorised by the chief executive to dispose of a voluntary assisted dying substance under the Act. It is intended to authorise all pharmacists at QVAD-Pharmacy, plus the pharmacist-in-charge of any other pharmacy in Queensland, including private and public hospital pharmacies, and community pharmacies, to be authorised disposers.

An authorised disposer and administering practitioner are authorised to possess a voluntary assisted dying substance for the purposes of disposal and are required to dispose of the voluntary assisted substance or unused or remaining substance as soon as practicable after receiving it. To ensure that a voluntary assisted dying substance is managed appropriately while in the community, there is a need to prescribe additional detail in relation to how the substance is to be destroyed.

Voluntary Assisted Dying Review Board

The Review Board's functions under the Act require the Review Board to monitor compliance with, and the operation of, the Act and the voluntary assisted dying scheme and to provide advice to the Minister or the chief executive on matters about the voluntary assisted dying scheme on the Review Board's own initiative or on request.

Section 117(1) of the Act outlines the functions of the Review Board. These functions include:

- monitoring the operation of the Act;
- reviewing for each completed request for voluntary assisted dying whether participating entities complied with the Act; and
- referring issues identified by the Review Board about voluntary assisted dying to any of the following entities if relevant to the entities' functions:
    - the Commissioner of Police;
    - the Registrar-General;
    - the State Coroner;
    - the Health Ombudsman;
    - the chief executive of Queensland Health.

These functions reflect the Review Board's primary purpose as an independent oversight body to monitor the operation of, and compliance with, the legislation by undertaking reviews of completed voluntary assisted dying requests and providing advice to the Minister and chief executive about the scheme. Section 117(1)(d) of the Act requires the Review Board to record and keep information prescribed by regulation about requests for, and provision of, voluntary assisted dying.

The Review Board is required to provide information, reports and advice to the Minister or the chief executive of Queensland Health about the operation of the Act, the Board's functions or the improvement of the processes and safeguards of voluntary assisted dying, either on the Review Board's own initiative or on request. This includes a requirement for the Review Board to provide an annual report to the Minister about the performance of the Board's functions (section 134 of the Act). The annual report must include particular information, including a de-identified summary of information required to be recorded and kept by the Review Board under section 117(1)(d) of the Act.

The QLRC report states that data collection, analysis and research is an important corollary to many of the Review Board's other functions and is necessary for its oversight role. It is particularly important for identifying patterns, trends or systemic issues, and monitoring the overall effectiveness of the legislation (paragraph 18.241).

Achievement of policy objectives

To achieve the policy objectives, the Regulation prescribes, in accordance with the Act:

- the technical requirements for the management of a voluntary assisted dying substance including the prescribing, labelling, supply, storage, and disposal of the substance; and
- information to be recorded and kept by the Review Board about requests for, and provision of, voluntary assisted dying.

The detail provided in the Regulation improves operational clarity of the management of the voluntary assisted dying substance. The information prescribed by the Regulation to be recorded and kept by the Review Board adds clarity to the Review Board's processes.

Prescribing

The Regulation achieves the policy objective of ensuring voluntary assisted dying substances are used safely and effectively and reduces the risk of causing harm to the public by ensuring the prescription for the substance from a coordinating practitioner contains the following:

- the coordinating practitioner's name;
- the place where the practitioner usually practices;
- the coordinating practitioner's phone number;
- date the prescription is issued;
- the address of the person who is accessing voluntary assisted dying; and
- the coordinating practitioner's signature.

The Regulation includes requirements the coordinating practitioner must follow when issuing a prescription for a voluntary assisted dying substance. The additional requirements prescribed by regulation for the written prescription will ensure coordinating practitioners are aware of what details are required to be included on the prescription, which in turn will also assist the QVAD-Pharmacy when the prescription is received. The requirements enhance the effectiveness and efficiency of the prescription process as the practitioner will be able to complete the prescription based on the additional technical details in the Regulation.

The prescribing requirements will provide clear obligations on the coordinating practitioner during the prescription process and provide an additional safeguard for the safe management of the voluntary assisted dying substance.

The coordinating practitioner will be responsible for completing the prescription for the voluntary assisted dying substance in accordance with the requirements in the Regulation. The prescription will be given directly from the coordinating practitioner to the authorised supplier at the QVAD-Pharmacy as required under the Act. The QVAD-Pharmacy is being established as a dedicated service within Queensland Health as part of the implementation of the voluntary assisted dying scheme.

Labelling

The Regulation achieves the policy objective by ensuring the authorised supplier must attach a label to the outside of the container or package of the voluntary assisted dying substance that states:

- the name, address and telephone number of the place where the authorised supplier supplied the substance;
- the approved name or brand name of the substance;
- the form and strength of the substance;
- the total quantity of the substance in the container or package;
- the words 'KEEP OUT OF REACH OF CHILDREN' in red, capital letters on a white background;
- the name of the person who is accessing voluntary assisted dying;

- the unique identifying number given to the prescription for the supply of the substance by the authorised supplier;
- the date the substance is supplied;
- the expiry date for the substance.

An authorised supplier must also attach a label to the outside of the container or package of the voluntary assisted dying substance that states the purpose of the dose of the substance is to cause death, that the substance must be stored as required under the Act and that any unused or remaining substance must be disposed of as required under the Act. The additional label must be written in the English language, in a colour to provide a distinct contract to the background colour and written in letters that are at least 1.5mm in height.

The labelling requirements provide clarity to the authorised supplier when supplying the voluntary assisted dying substance by listing the information and warnings that must be included. This will protect the community by ensuring any voluntary assisted dying substance that is supplied is appropriately labelled.

Supply

The Regulation achieves the policy objective by ensuring the authorised supplier must keep the original prescription for at least two years after the day the voluntary assisted dying substance was supplied.

The authorised supplier must not supply the voluntary assisted dying substance if the prescription for the substance was issued more than six months before the day the substance is to be supplied.

The supply requirements will ensure authorised suppliers are able to confirm the prescription is still valid and can review prescriptions that have been processed. This supports the important role of authorised suppliers in providing essential oversight of the supply process for the voluntary assisted dying substance.

Storage

The Regulation achieves the policy objective by prescribing storage requirements that the voluntary assisted dying substance must be stored in a locked box that is not easily penetrable and lockable with a lock of sturdy construction. The box may only be unlocked if the voluntary assisted dying substance is being prepared, administered or disposed of.

The storage requirements in the Regulation apply to a person that receives the voluntary assisted dying substance, including the person, contact person or their agent for self-administration, or the administering practitioner for practitioner administration.

The storage requirements for a voluntary assisted dying substance that is received for self-administration and practitioner administration have been aligned for consistency and will ensure the voluntary assisted dying substance is managed safely once it has left control of the authorised supplier.

Disposal

The Regulation achieves the policy objective by prescribing the disposal requirements for an authorised disposer or administering practitioner to personally destroy the voluntary assisted dying substance, or any unused or remaining substance, by disposing of it in a way that renders the substance unusable and unidentifiable by any person.

The disposal requirements will provide the authorised disposer and administering practitioner clear instructions on the appropriate way to dispose of the voluntary assisted dying substance. These requirements ensure accountabilities for managing the substance once the person who accessed the scheme has died or has revoked their administration decision.

The QVAD-Pharmacy will be available to provide guidance on disposal to the administering practitioner or authorised disposer, including community pharmacies that receive the substance for disposal.

Voluntary Assisted Dying Review Board

The Regulation achieves the policy objective by prescribing the information required to be recorded and kept by the Review Board about requests for, and provision of, voluntary assisted dying. This includes:

- the number of people assessed as eligible or ineligible for access to voluntary assisted dying in a first assessment;
- the number of people assessed as eligible or ineligible for access to voluntary assisted dying in a consulting assessment;
- for each person assessed in a first assessment – their age, sex, and the region where the person lives;
- for each person assessed as eligible to access voluntary assisted dying in a first assessment and consulting assessment – the disease, illness or medical condition with which the person has been diagnosed;
- the number of completed requests for voluntary assisted dying, as defined under 117(2) of the Act;
- for each completed request for voluntary assisted dying:
  - whether the person has died, and if so, whether the person died:
    - following self-administration of a voluntary assisted dying substance; or
    - following the administration of a voluntary assisted dying substance by an administering practitioner; or
    - without the administration of a voluntary assisted dying substance; or
  - whether the request was discontinued; and
- for each person who has made a final request – the time between the first and final requests;
- the number of medical practitioners who have been involved in requests for, or provision of, voluntary assisted dying;
- the number of nurse practitioners who have been involved in the provision of voluntary assisted dying; and
- the number of nurses who have been involved in the provision of voluntary assisted dying.

This information will provide visibility on the access to the provision of voluntary assisted dying scheme. For example, the prescribed information includes, for a person who has undergone a first assessment, the region where they live. This will provide transparency on demand for and access to voluntary assisted dying across Queensland and ensure that equity of access is monitored and reported on.

The Regulation provides a baseline of key information the Review Board must record, keep and report in a de-identified form. Prescribing the information that is required to be recorded and kept supports the Review Board in undertaking its functions and the requirement to include the information in an annual report in accordance with section 134 of the Act. It also provides transparency to the community about the operation of the scheme by ensuring a baseline of key information the Review Board must report.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The Regulation does not impose significant costs on the persons or organisations to which they apply. The costs of implementing the scheme will be met within existing budget allocations.

The Regulation will support the Act and the operation of the voluntary assisted dying scheme. Prescribing these matters by regulation is appropriate noting they are minor and technical in nature and will enable the requirements to be refined in future if necessary.

Including technical requirements about the prescribing, labelling, supply, storage, and disposal of the voluntary assisted dying substance will ensure that specific requirements relating to the management of the substance are clear for practitioners.

The inclusion in the Regulation of the information to be recorded, kept and reported on by the Review Board will ensure transparency of the Review Board's processes.

Consistency with fundamental legislative principles

The regulation is consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Consultation

Extensive consultation was undertaken before and during development of the Voluntary Assisted Dying Bill 2021 and the QLRC Report.

The Regulation is intended to support the Act by prescribing technical matters about the management of the voluntary assisted dying substance and the information to be recorded and kept by the Review Board.

In June 2022, key pharmacy stakeholders were consulted about the Regulation, including the Society of Hospital Pharmacists Australia (Queensland Branch), Pharmaceutical Society of Australia (Queensland Branch), Pharmacy Guild of Australia (Queensland Branch) and internal pharmacy stakeholders within Queensland Health. Feedback received was minimal and was considered as part of finalising the Regulation.

A preliminary impact assessment was undertaken by Queensland Health in accordance with *The Queensland Government Guide to Better Regulation*. The Office of Best Practice Regulation, Queensland Treasury was consulted on the preliminary impact assessment and advised that the proposal appears unlikely to result in adverse impacts and that no further regulatory analysis is required.

Notes on provisions

Part 1 Preliminary

Short Title

Clause 1 provides the short title of the regulation is the *Voluntary Assisted Dying Regulation 2022*.

Commencement

Clause 2 states the regulation commences on 1 January 2023.

Part 2 Prescribing, supplying and disposing of voluntary assisted dying substance

Other requirements for prescribing—Act, s 67

Clause 3 prescribes other requirements for prescribing under section 67 of the *Voluntary Assisted Dying Act 2021* (Act).

Clause 3(2) provides a coordinating practitioner must state on the prescription for the voluntary assisted dying substance the following information:

- coordinating practitioner's name;
- place where the coordinating practitioner usually practices;
- coordinating practitioner's phone number;
- date the prescription is issued;
- address of the person who is accessing voluntary assisted dying.

Clause 3(3) requires the coordinating practitioner to sign the prescription.

Labelling requirements for voluntary assisted dying substance—Act, s 71

Clause 4 prescribes the labelling requirements for a voluntary assisted dying substance under section 71 of the Act.

Clause 4(2) provides that the authorised supplier must attach a label to the outside of the container or package of the voluntary assisted dying substance stating the following information:

- name, address and telephone number of the place where the authorised supplier supplied the substance;
- approved name or brand name of the substance;
- form and strength of the substance;
- total quantity of the substance in the container or package;
- the words 'keep out of reach of children' in red, capital letters on a white background;

- name of the person who is accessing voluntary assisted dying;
- the unique identifying number given to the prescription for the supply of the substance by the authorised supplier;
- date the substance is supplied;
- the date on which the substance is due to expire.

Clause 4(3) provides that an authorised supplier must attach another label to the outside of the container or package of the voluntary assisted dying substance that states the following information:

- the purpose of the dose of the substance is to cause death;
- the substance must be stored as required under the Act;
- any unused or remaining substance must be disposed of as required under the Act.

Clause 4(4) provides that a word required under subclause (2) or (3) to be written on a label must:

- be written in the English language; and
- be written in letters that are at least 1.5mm in height; and
- be written be written in a colour that provides a distinct contract to the background colour, for a word other than a word mentioned in subsection (2)(e).

Clause 4(5) provides that for this section, *approved name* is defined in part 1 of the Poisons Standard. The Poisons Standard means the current Poisons Standard within the meaning of section 52A(1) of the *Therapeutic Goods Act 1989* (Cwlth).

Other requirements for supplying—Act, s 73

Clause 5 prescribes other requirements for supplying under section 73 of the Act.

Clause 5(2) provides that the authorised supplier must not supply the voluntary assisted dying substance if the prescription for the substance was issued more than six months before the day the substance is to be supplied.

Clause 5(3) provides that the authorised supplier must keep the prescription for at least two years after the day the voluntary assisted dying substance was supplied.

Storage of voluntary assisted dying substance—Act, s 74

Clause 6 establishes for section 74 of the Act, the storage requirements of a voluntary assisted dying substance.

Clause 6(2) provides that the person must store the voluntary assisted dying substance in a box that is:

- not easily penetrable; and
- lockable with a lock of sturdy construction.

Clause 6(3) provides that the person must immediately lock the box and keep the box locked unless the voluntary assisted dying substance is being prepared, administered or disposed of.

Other requirement for disposal—Act, s 79

Clause 7 prescribes for section 79 of the Act, that the authorised disposer or administering practitioner must personally destroy the voluntary assisted dying substance or any unused or remaining substance.

Clause 7(2) provides that the definition of *destroy* a voluntary assisted dying substance or unused or remaining substance, means dispose of the substance in a way that renders it unusable and unidentifiable by any person.

Part 3 Voluntary Assisted Dying Review Board

Function of board to record and keep information—Act, s 117

Clause 8 provides that for section 117(1)(d) of the Act, the following information is prescribed:

- the number of people assessed, whether as eligible or ineligible, for access to voluntary assisted dying in a first assessment;
- the number of people assessed, whether as eligible or ineligible, for access to voluntary assisted dying in a consulting assessment;
- for each person assessed in a first assessment, the age and sex of the person and the region where the person lives;
- for each person assessed as eligible to access voluntary assisted dying in a first assessment and consulting assessment, the disease, illness or medical condition with which the person has been diagnosed;
- the number of completed requests for voluntary assisted dying, as defined under section 117(2) of the Act;
- for each completed request for voluntary assisted dying:
  - whether the person has died, and if so, whether the person died:
    - following self-administration of a voluntary assisted dying substance; or
    - following the administration of a voluntary assisted dying substance by an administering practitioner; or
    - without the administration of a voluntary assisted dying substance; or
  - whether the request was discontinued;
- for each person who has made a final request, the period between the first request and the final request;
- the number of medical practitioners who have been involved in requests for, or provision of, voluntary assisted dying;
- the number of nurse practitioners who have been involved in the provision of voluntary assisted dying; and
- the number of nurses who have been involved in the provision of voluntary assisted dying.