Queensland

Public Health (Medicinal Cannabis) Act 2016

Public Health (Medicinal Cannabis) Regulation 2017

Current as at 1 January 2018

Queensland

Public Health (Medicinal Cannabis) Regulation 2017

Contents

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Public Health (Medicinal Cannabis) Regulation 2017

Part 1 Introduction

Division 1 Preliminary

1 Short title

This regulation may be cited as the *Public Health (Medicinal Cannabis) Regulation 2017*.

2 Commencement

This regulation commences on 1 March 2017.

3 Definitions

The dictionary in schedule 2 defines particular words used in this regulation.

Division 2 General provisions

4 Compliance with code, guideline, protocol or standard

(1) This section applies if—

(a) under this regulation, a person must comply with a requirement of a code, guideline, protocol or standard; or

(b) a standard states a way of complying with a requirement of the regulation.

(2) If the requirement or way (the ***inconsistent requirement***) is inconsistent with a provision of the regulation, the provision of the regulation prevails to the extent of any inconsistency.

(3) However, in a proceeding against a person for an offence relating to the provision, it is a defence for the person to show the person complied with the inconsistent requirement.

5 Language of documents

(1) A person who is required under this regulation to give, issue or keep a document must write the document in English.

Maximum penalty—20 penalty units.

(2) However, the person may also write the document in another language if it is reasonably necessary to ensure a person named in the document understands any instructions given in the document.

Example—

The instructions on medicinal cannabis dispensed for someone who does not speak English may be both in English and the language the person speaks.

Part 2 Manufacturing approvals and wholesaling approvals

Division 1 Preliminary

6 Definitions for part

In this part—

amendment application see section 30.

application means the following applications made under this part—

(a) an original application for an approval;

(b) an amendment application for an approval;

(c) a replacement application for an approval;

(d) a renewal application for an approval.

approval means a manufacturing approval or a wholesaling approval.

information requirement notice, for an application, means a notice—

(a) given to the applicant by the chief executive; and

(b) stating the information the chief executive reasonably considers is required from the applicant to decide the application.

manufacturer means the holder of a manufacturing approval.

manufacturing approval see section 12.

renewal application see section 34.

replacement application see section 32.

7 Consistency with Commonwealth law

This part applies to the manufacture of medicinal cannabis only to the extent this part is consistent with Commonwealth law.

Note—

See 217(2)(e) of the Act for the power to make regulations under the Act about the manufacture of medicinal cannabis.

8 Evidentiary aids

A certificate purporting to be signed by the chief executive stating any of the following matters is evidence of the matter—

(a) a stated document is an approval;

(b) a stated document is a copy of, or an extract from a part of, an approval;

(c) on a stated day, or during a stated period, a stated person was or was not the holder of an approval;

(d) on a stated day, or during a stated period, an approval—

(i) was or was not in force; or

(ii) was or was not subject to a stated condition;

(e) on a stated day an approval was suspended for a stated period, surrendered or cancelled.

Division 2 Application for approvals

Subdivision 1 Preliminary

9 Suitability of person to hold approval

(1) In deciding whether a person is a suitable person to hold, or to continue to hold, an approval the chief executive may have regard to, and may make inquiries about, the following—

(a) the person's qualifications and experience;

(b) the person's character and standing;

(c) whether the person engages, or has engaged, in conduct that risks, or is likely to risk, medicinal cannabis being used for a purpose that is unlawful under a law of a State or the Commonwealth;

(d) the person's knowledge and understanding of the applicant's obligations under the Act;

(e) whether the person, in the chief executive's reasonable opinion, will be able to comply with—

(i) the Act; and

(ii) the conditions proposed to apply to the approval;

(f) whether the person—

(i) has held a similar instrument under a relevant law that was suspended, cancelled or had conditions imposed on it; or

(ii) has been refused a similar instrument under a relevant law.

(2) Subsection (1) does not limit the matters to which the chief executive may have regard in considering the suitability of the person to hold an approval.

10 Approved form

An application must be in the approved form, if any.

Subdivision 2 Particular provisions for application for manufacturing approval

11 Purpose of subdivision

This subdivision states particular matters relating to applications for manufacturing approvals.

12 Who may apply for manufacturing approval

A person may apply for an approval (a ***manufacturing approval***) to manufacture medicinal cannabis.

13 Criteria for grant or renewal of manufacturing approval

(1) In considering an application for the grant or renewal of a manufacturing approval the chief executive may consider the following—

(a) whether the applicant is a suitable person to hold the approval;

(b) whether the applicant intends to carry on business as a manufacturer of medicinal cannabis;

(c) whether each individual who holds, or will hold, the position responsible for supervising the manufacture of each type or form of medicinal cannabis under the approval has the qualifications and experience necessary to effectively supervise the manufacture;

(d) the suitability of the premises used, or to be used, for manufacturing the medicinal cannabis;

(e) any other information in the application for the approval;

(f) any other matters the chief executive reasonably considers relevant to deciding the application.

(2) Without limiting subsection (1), the chief executive may grant a manufacturing approval only if the chief executive is satisfied of the following matters—

(a) the applicant is a suitable person to hold the approval;

(b) the applicant intends to carry on business as a manufacturer of medicinal cannabis;

(c) each individual who holds, or will hold, the position responsible for supervising the manufacture of each type or form of medicinal cannabis under the approval has the qualifications and experience necessary to effectively supervise the manufacture;

(d) the premises used, or to be used, for manufacturing the medicinal cannabis are suitable for that purpose.

Subdivision 3 Particular provisions for application for wholesaling approval

14 Purpose of subdivision

This subdivision states particular matters relating to applications for wholesaling approvals.

15 Who may apply for wholesaling approval

A person may apply for an approval (a ***wholesaling approval***) to wholesale medicinal cannabis to persons mentioned in section 38(1)(b).

16 Criteria for grant or renewal of wholesaling approval

(1) In considering an application for the grant or renewal of a wholesaling approval the chief executive may consider the following—

(a) whether the applicant is a suitable person to hold the approval;

(b) whether the applicant intends to carry on business as a wholesaler of medicinal cannabis;

(c) the suitability of the premises used, or to be used, for wholesaling the medicinal cannabis;

(d) any other information in the application for the approval;

(e) any other matters the chief executive reasonably considers relevant to deciding the application.

(2) Without limiting subsection (1), the chief executive may grant a wholesaling approval only if the chief executive is satisfied of the following matters—

(a) the applicant is a suitable person to hold the approval;

(b) the applicant intends to carry on business as a wholesaler of medicinal cannabis;

(c) the premises used, or to be used, for wholesaling the medicinal cannabis are suitable for that purpose.

Subdivision 4 Process for deciding applications

17 Decision on application for approval

(1) The chief executive must consider an application and decide to—

(a) grant the application; or

(b) grant the application subject to conditions; or

(c) refuse to grant the application.

(2) If the chief executive decides to grant the application, the chief executive must—

(a) if the application is for the grant of an approval—give the applicant the approval; or

(b) if the application is an amendment application for an approval—

(i) endorse the approval with the amendment; or

(ii) cancel the approval and give the approval holder a new approval with the amendment; or

(c) if the application is a replacement application for an approval—give the approval holder the replacement approval; or

(d) if the application is a renewal application for an approval—give the approval holder the new approval.

(3) If the chief executive decides to endorse or cancel an approval, the chief executive must, as soon as practicable, give the approval holder a notice requiring the approval holder to return the instrument for the approval.

(4) The chief executive must give the applicant an information notice about the following decisions, as soon as practicable after the decision is made—

(a) a decision to refuse to grant the application for the approval;

(b) a decision to impose conditions on the approval, other than conditions sought by the applicant.

18 Chief executive may require information or documents

(1) Before deciding an application for an approval, the chief executive may investigate the applicant.

(2) The chief executive may give the applicant an information requirement notice—

(a) for a renewal application—within 14 days after the chief executive receives the application; or

(b) for another application—within 60 days after the chief executive receives the application.

(3) The information requirement notice must state a reasonable period for compliance with the notice that is—

(a) for a renewal application—at least 14 days after the giving of the notice; or

(b) for another application—at least 30 days after the giving of the notice.

(4) The information required under the information requirement notice must be verified by statutory declaration if the notice requires it.

(5) The applicant is taken to have withdrawn the application if the applicant does not comply with the information requirement notice.

19 Chief executive may extend period for decision for complex application

(1) This section applies if the chief executive considers that, because of the complexity of the matters to be decided for an application, the chief executive needs extra time to consider the application.

(2) The chief executive—

(a) may extend the period for considering the application by the reasonable number of days the chief executive considers necessary to decide the application; and

(b) must give the applicant notice of the day the extended period ends.

20 Failure to decide application

(1) Subject to subsections (2) and (3), the chief executive is taken to have refused to grant an application for an approval if the chief executive fails to decide the application—

(a) for an original application for an approval—within 90 days after the chief executive receives the application; or

(b) for a renewal application for an approval—within 30 days after the chief executive receives the application; or

(c) for another application for an approval—within 60 days after the chief executive receives the application.

(2) If the chief executive has given the applicant an information requirement notice, a period mentioned in subsection (1) starts from the day the chief executive receives the information required under the information requirement notice.

(3) If the chief executive has extended the period for deciding the application for the approval under section 19, the chief executive is taken to have refused to grant the application if the chief executive does not decide the application within the extended period.

(4) If the chief executive is, under this section, taken to have refused to grant an application, the chief executive must give the applicant for the application an information notice for the deemed refusal.

Division 3 Grant of approvals

Subdivision 1 Conditions, term and transfer

21 Standard conditions for manufacturing approvals

A manufacturing approval is subject to the following standard conditions—

(a) the manufacturer must not manufacture or possess medicinal cannabis at a place other than the manufacturer's business premises stated in the approval;

(b) the manufacturer must ensure each type or form of medicinal cannabis manufactured under the approval is

manufactured under the personal supervision of an individual, named in the approval, who—

(i) holds the position responsible for supervising the manufacture of the type or form of medicinal cannabis; and

(ii) is present at the premises used for manufacturing the medicinal cannabis during the manufacture;

(c) the premises used for manufacturing the medicinal cannabis must be suitable for that purpose.

22 Standard conditions for wholesaling approvals

A wholesaling approval is subject to the following standard conditions—

(a) the wholesaler must not possess or wholesale medicinal cannabis at a place other than the wholesaler's business premises stated in the approval;

(b) the wholesaler must ensure medicinal cannabis at the wholesaler's business premises is not handled by a person other than the wholesaler or a competent adult employee of the wholesaler;

(c) the wholesaler must not wholesale medicinal cannabis to a person who is not mentioned in section 38(1)(b);

(d) the premises used for wholesaling the medicinal cannabis must be suitable for that purpose.

23 Additional or varied conditions for approvals

(1) This section applies if the chief executive reasonably believes it is necessary for an additional or varied condition to apply to an approval.

(2) The chief executive, when granting the approval, may—

(a) impose additional conditions for the approval; or

(b) vary a standard condition by stating the variation in the instrument for the approval.

24 Term of approvals

An approval remains in force for the term, not more than 2 years, decided by the chief executive and stated in the approval, unless sooner cancelled, suspended or surrendered.

25 Transfer of approvals prohibited

An approval can not be transferred.

Subdivision 2 Form of approvals

26 Form of manufacturing approval

An instrument for a manufacturing approval must contain the following information—

(a) the manufacturer's name and professional qualifications;

(b) the name of the business, and address of both the business and premises, the manufacturer will use to manufacture medicinal cannabis;

(c) the term of the approval;

(d) the conditions applying to the approval;

(e) the type and form of medicinal cannabis that may be manufactured under the approval;

(f) for each type or form of medicinal cannabis mentioned in paragraph (e)—the name of an individual who holds the position responsible for supervising the manufacture of the type or form of medicinal cannabis.

27 Form of wholesaling approval

An instrument for a wholesaling approval must contain the following information—

(a) the wholesaler's name and professional qualifications;

(b) the name of the business, and address of both the business and premises, the wholesaler will use to wholesale medicinal cannabis;

(c) the term of the approval;

(d) the conditions applying to the approval;

(e) the type and form of medicinal cannabis that may be sold under the approval.

Division 4 Amendment, replacement and renewal of approvals

Subdivision 1 Preliminary

28 Making applications

An application for the amendment, replacement or renewal of an approval must be—

(a) made to the chief executive; and

(b) in the approved form.

29 Process for deciding application

Subject to this division, an application for the amendment, replacement or renewal of an approval must be decided under part 2, division 2, subdivision 4.

Subdivision 2 Amendment

30 Application by holder to amend approval

The holder of an approval may apply (an ***amendment application*** for the approval) to the chief executive to amend the approval in relation to the following—

(a) the type or form of medicinal cannabis that may be manufactured or wholesaled under the approval;

(b) the conditions applying to the approval;

(c) another thing stated in the approval.

31 Minor amendment of approval by chief executive

(1) The chief executive may decide to amend an approval, on the chief executive's own initiative, if the amendment is only for—

(a) a formal or clerical reason; or

(b) another reason if the chief executive reasonably believes the amendment will not adversely affect the interests of the approval holder.

(2) The chief executive must give notice of the following to the approval holder as soon as practicable after the chief executive decides to make the amendment—

(a) the amendment decided by the chief executive;

(b) the reason for the amendment;

(c) if the chief executive decides to endorse the instrument for the approval—that the holder must return the instrument to the chief executive to be endorsed.

Subdivision 3 Replacement

32 Application for replacement of approval

The holder of an approval may apply (a ***replacement application*** for the approval) for the replacement of the approval if the instrument for the approval has been damaged, destroyed, lost or stolen.

33 Criteria for deciding replacement application

The chief executive may grant the replacement application for the approval if the chief executive is reasonably satisfied the instrument for the approval has been damaged, destroyed, lost or stolen.

Subdivision 4 Renewal

34 Application for renewal of approval

(1) The holder of an approval may apply to the chief executive to renew the approval (a ***renewal application*** for the approval) within the period starting 60 days before the term of the approval ends.

(2) Despite subsection (1), the chief executive may accept a renewal application for the approval made within 30 days after the term of the approval ends if the chief executive is satisfied it is reasonable to do so in the circumstances.

35 Approval taken to be in force while renewal application considered

(1) This section applies if a renewal application for an approval is made before the approval expires.

(2) The approval is taken to continue in force from the day that, apart from this section, the approval would have expired.

(3) Subsection (2) applies until the application is—

(a) decided under section 17; or

(b) taken to have been withdrawn under section 18.

(4) However, if the application is refused, or taken to be refused under section 20, the approval continues in force until the information notice for the refusal is given to the applicant.

(5) Subsection (2) does not apply if the approval is earlier suspended or cancelled under division 8.

Division 5 Return and surrender of approvals

36 Return of instrument of approval

(1) This section applies if—

(a) the chief executive gives a notice to an approval holder that requires the holder to return the original instrument for the approval to the chief executive; or

(b) the approval holder receives a replacement instrument for the approval and subsequently finds the original instrument for the approval.

(2) The approval holder must return the original instrument for the approval to the chief executive within 1 of the following periods, unless the holder has a reasonable excuse—

(a) if the holder has received a notice from the chief executive—7 days after receiving the notice;

(b) if the holder finds the original instrument for the approval—as soon as practicable after finding the instrument.

Maximum penalty—20 penalty units.

Division 6 Authority under approvals

37 Manufacturing approval does not grant authority to manufacture

A manufacturing approval does not, of itself, grant the manufacturer authority to manufacture medicinal cannabis under the Act.

Note—

Under section 92(2)(b) of the Act, a person may manufacture medicinal cannabis if the person is, in accordance with an applicable law of the Commonwealth, authorised to manufacture medicinal cannabis.

38 Authority under wholesaling approval

(1) A wholesaler is authorised to—

(a) obtain the type and form of medicinal cannabis stated in the approval; and

(b) wholesale the type and form of medicinal cannabis stated in the approval, whether or not for resale, to—

(i) a single-patient prescriber; or

(ii) a patient-class prescriber; or

(iii) a pharmacist; or

(iv) someone in another State who may obtain the medicinal cannabis under the law of the other State; and

(c) temporarily possess the medicinal cannabis until the wholesaler sells the medicinal cannabis.

(2) The wholesaler must exercise the authority under subsection (1)—

(a) in accordance with the Act; and

(b) if the approval, or the conditions imposed on the approval, restricts or states the way in which the wholesaler may exercise the authority—in accordance with the restriction or stated way.

Division 7 Particular provisions for wholesaling approvals

39 Wholesaling code

(1) Subject to subsection (2), a wholesaler must, when exercising the wholesaler's authority under section 38, comply with the code entitled the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8.

Maximum penalty—20 penalty units.

Note—

The code is available on the Therapeutic Goods Administration's website.

(2) Subsection (1) does not apply to the wholesaler to the extent the wholesaler carries on business under the wholesaling approval in a way that does not require the wholesaler to store, handle or transport medicinal cannabis.

40 Wholesaler to give invoice when wholesaling medicinal cannabis

(1) A wholesaler must, when wholesaling medicinal cannabis to a person, give the person an invoice for the wholesale of the medicinal cannabis that complies with subsection (2).

Maximum penalty—20 penalty units.

(2) The invoice must—

(a) have a unique number; and

(b) state—

(i) the date of the wholesale; and

(ii) the name and address of the person to whom the medicinal cannabis was sold; and

(c) describe the type and form, and quantity or volume, of the medicinal cannabis sold.

41 Automatic grant, renewal, variation, suspension, cancellation and surrender of wholesaling approval

(1) If the chief executive grants a person a manufacturing approval, the chief executive must, when granting the manufacturing approval, also grant the person a wholesaling approval (the ***automatic approval***)—

(a) for the type and form of medicinal cannabis the person may manufacture under the manufacturing approval; and

(b) for the same term as the manufacturing approval.

(2) If the chief executive renews the manufacturing approval, the chief executive must, when renewing the manufacturing approval, also renew the automatic approval for the same term as the manufacturing approval.

(3) If the chief executive varies the type or form of medicinal cannabis the person may manufacture under the manufacturing approval, or amends the manufacturing approval in another way, the chief executive must, when amending the manufacturing approval, also amend the automatic approval in the same way.

(4) If the chief executive suspends the manufacturing approval, the chief executive must, when suspending the manufacturing approval, also suspend the automatic approval for the same period.

(5) If the chief executive cancels the manufacturing approval, the chief executive must, when cancelling the manufacturing approval, also cancel the automatic approval.

(6) If the person surrenders the manufacturing approval, the person is also taken to have surrendered the automatic approval.

Division 8 Administrative action

42 Definition for division

In this division—

administrative action, in relation to an approval, means—

(a) suspension of the approval; or

(b) cancellation of the approval; or

(c) variation of the approval; or

(d) imposition of conditions on the approval.

43 Grounds for action to be taken

Each of the following is a ground for the chief executive to take administrative action in relation to an approval—

(a) the approval holder has contravened the Act or a condition of the approval;

(b) the chief executive believes the administrative action is necessary to prevent or minimise a diversion risk or a substance risk;

(c) the approval holder is not, or is no longer, suitable to hold the approval;

(d) the approval holder made a materially false or misleading representation or declaration to obtain the approval.

44 Show cause notice

(1) This section applies if the chief executive reasonably believes a ground exists to take administrative action in relation to an approval.

(2) The chief executive must give the approval holder a notice under this section (a ***show cause notice***).

(3) The show cause notice must state the following—

(a) the administrative action (the ***proposed action***) in relation to the approval the chief executive proposes to take;

(b) the grounds for the proposed action;

(c) an outline of the facts and circumstances forming the basis for the grounds;

(d) if the proposed action is a suspension of the approval—the proposed suspension period;

(e) if the proposed action is a variation of the approval—details of the variation;

(f) if the proposed action is the imposition of conditions—details of the conditions;

(g) an invitation to the approval holder to show within a stated period (the ***show cause period***) why the proposed action should not be taken.

(4) The show cause period must be a period ending not less than 21 days after the show cause notice is given to the approval holder.

45 Representations about show cause notices

(1) The approval holder may make written representations to the chief executive about the show cause notice given to the holder within the show cause period for the notice.

(2) The chief executive must consider all representations (the ***accepted representations***) made under subsection (1).

46 Ending show cause process without further action

(1) This section applies if, after considering the accepted representations from the approval holder for the show cause notice, the chief executive no longer believes a ground exists to take administrative action in relation to the approval.

(2) The chief executive must not take any further action about the show cause notice.

(3) The chief executive must give notice to the holder that no further action is to be taken about the show cause notice.

47 Decision to take administrative action

(1) This section applies if, after considering the accepted representations from the approval holder for the show cause notice, the chief executive—

(a) still reasonably believes a ground exists to take administrative action in relation to the approval; and

(b) reasonably believes the administrative action is warranted.

(2) This section also applies if there are no accepted representations for the show cause notice.

(3) The chief executive may decide—

(a) if the proposed action stated in the show cause notice was to suspend the approval for a stated period—to suspend the approval for no longer than the stated period; or

(b) if the proposed action stated in the show cause notice was to cancel the approval—to either cancel the approval or suspend it for a period; or

(c) if the proposed action stated in the show cause notice was to vary the approval—to either vary the approval as proposed or vary the approval in a less onerous way; or

(d) if the proposed action stated in the show cause notice was to impose conditions on the approval—to either impose the conditions proposed or impose less onerous conditions on the approval.

(4) As soon as practicable after making the decision, the chief executive must give an information notice about the decision to the approval holder.

(5) The decision takes effect on—

(a) the day the information notice is given to the holder; or

(b) if a later day of effect is stated in the information notice—the later day.

48 Immediate administrative action

(1) The chief executive may decide to immediately take administrative action in relation to an approval if the chief executive reasonably believes—

(a) a ground exists to take the administrative action in relation to the approval; and

(b) it is necessary to take the administrative action immediately because there is an imminent and serious risk to the life, health or safety of a person.

(2) The administrative action in relation to the approval—

(a) takes effect when both of the following notices are given to the approval holder—

(i) a show cause notice for the administrative action;

(ii) an information notice for the chief executive's decision to take the action; and

(b) continues in effect until the earliest of the following—

(i) the chief executive decides to stop the administrative action;

(ii) the show cause notice is finally dealt with;

(iii) 60 days after the day the notices were given to the holder.

Division 9 Offences

49 Offence for false or misleading statements or documents

A person must not state anything, or give a document containing information, the person knows is false or misleading in a material particular in relation to—

(a) an application for an approval; or

(b) an application for the amendment, replacement or renewal of an approval; or

(c) a response to a request for information under section 18 from the chief executive.

Maximum penalty—20 penalty units.

50 Offence for failure to comply with approval conditions

A person must comply with the conditions of an approval that apply to the person, unless the person has a reasonable excuse.

Maximum penalty—20 penalty units.

Part 3 Other dealings with medicinal cannabis

Division 1 Medicinal cannabis approvals, dispensing approvals and clinical trial approvals

51 Standard conditions for medicinal cannabis approvals—Act, s 34(1)

(1) For section 34(1) of the Act, the following conditions are prescribed as standard conditions for medicinal cannabis approvals—

(a) the approval holder's endorsement, under section 58 of the *Health (Drugs and Poisons) Regulation 1996*, must not be suspended or cancelled;

(b) the approval holder must maintain a current registration (the ***registration***), as a medical practitioner, under the Health Practitioner Regulation National Law;

(c) the registration must not be subject to a condition or undertaking prohibiting the approval holder from performing an act that—

(i) is in the scope of the approval holder's authority; or

(ii) involves a controlled drug;

(d) if a TGA approval is stated in the medicinal cannabis approval—the approval holder must comply with any conditions imposed on the TGA approval;

(e) if the patient is a driving restricted patient—the approval holder must—

(i) obtain a written driving acknowledgement from the patient before exercising the approval holder's authority in relation to the patient; and

(ii) keep the written driving acknowledgement.

Note—

For requirements relating to the keeping of records and information, see part 6.

(2) In this section—

authority, of the holder of a medicinal cannabis approval, means the authority of the approval holder under section 57 of the Act.

driving restricted patient means a patient who—

(a) is at least 16 years old; and

(b) has capacity to consent to treatment with medicinal cannabis; and

(c) will, under the patient's medicinal cannabis approval, be treated with medicinal cannabis containing delta-9-tetrahydrocannabinol.

52 Standard conditions for dispensing approvals—Act, s 34(1)

(1) For section 34(1) of the Act, the following conditions are prescribed as standard conditions for dispensing approvals—

(a) the approval holder's endorsement, under section 64 of the *Health (Drugs and Poisons) Regulation 1996*, must not be suspended or cancelled;

(b) the approval holder must maintain a current registration (the ***registration***), as a pharmacist, under the Health Practitioner Regulation National Law;

(c) the registration must not be subject to a condition or undertaking prohibiting the approval holder from performing an act that—

(i) is in the scope of the approval holder's authority; or

(ii) involves a controlled drug;

(d) if a TGA approval relates to medicinal cannabis obtained, possessed, dispensed or manufactured by the approval holder—the approval holder must comply with any conditions imposed on the TGA approval;

(e) the approval holder must only dispense medicinal cannabis in accordance with a prescription;

(f) the approval holder must comply with the Guidelines for Dispensing of Medicines published by the Pharmacy Board of Australia.

Note—

The Guidelines for Dispensing of Medicines is available on the Pharmacy Board of Australia's website.

(2) In this section—

authority, of the holder of a dispensing approval, means the authority of the approval holder under section 58 of the Act.

manufacture means manufacture within the meaning of the Act, schedule 1, definition *manufacture*, paragraph (a)(vi) to (viii).

53 Standard conditions for clinical trial approvals—Act, s 34(1)

(1) For section 34(1) of the Act, the condition stated in subsection (2) is prescribed as a standard condition for clinical trial approvals.

(2) If an ethics committee has approved a protocol for the clinical trial to which the clinical trial approval relates, the clinical trial must be conducted in accordance with the requirements of the protocol.

(3) In this section—

ethics committee see the *Therapeutic Goods Act 1989* (Cwlth), section 3.

Division 2 Patient-class prescribers

54 Prescribed specialist medical practitioners—Act, s 52(1)(a)

(1) For section 52(1)(a) of the Act, the following classes of specialist medical practitioners are prescribed—

(a) compliant palliative medicine specialists;

(b) compliant specialist general paediatricians;

(c) compliant specialist gynaecological oncologists;

(d) compliant specialist haematologist physicians;

(e) compliant specialist medical oncologists;

(f) compliant specialist neurologists;

(g) compliant specialist paediatric medical oncologists;

(h) compliant specialist paediatric neurologists;

(i) compliant specialist paediatric palliative medicine physicians;

(j) compliant specialist radiation oncologists.

(2) In this section—

compliant, in relation to a specialist medical practitioner, means a specialist medical practitioner who—

(a) is not breaching a condition applying to patient-class prescribers under section 57(2)(a) or (b); and

(b) has not breached a condition applying to patient-class prescribers under section 57(2)(c) to (f).

55 Prescribed classes of patients—Act, s 52(2)(a)

(1) For section 52(2)(a) of the Act, the following classes of patients are prescribed—

(a) persons experiencing chemotherapy-induced nausea or vomiting;

(b) terminally ill persons being treated by a compliant palliative medicine specialist for symptoms associated with terminal illness;

(c) children with intractable (drug resistant) epilepsy;

(d) persons with multiple sclerosis experiencing spasticity.

(2) In this section—

terminally ill person means a person who—

(a) has a terminal illness; and

(b) is, in the opinion of a compliant palliative medicine specialist treating the person, reasonably expected to die within 1 year as a result of the terminal illness.

56 Prescribed medicinal cannabis—Act, s 52(2)(b)

For section 52(2)(b) of the Act, medicinal cannabis containing either or both of the following is prescribed—

(a) delta-9-tetrahydrocannabinol;

(b) cannabidiol.

57 Conditions for patient-class prescribers—Act, s 52(1)(b)

(1) This section prescribes conditions for section 52(1)(b) of the Act.

(2) A patient-class prescriber's authority is conditional on the following—

(a) the patient-class prescriber's endorsement, under section 58 of the *Health (Drugs and Poisons) Regulation 1996*, must not be suspended or cancelled;

(b) the patient-class prescriber must maintain a current registration (the ***registration***), as a medical practitioner, under the Health Practitioner Regulation National Law;

(c) the registration must not be subject to a condition or undertaking prohibiting the patient-class prescriber from performing an act that—

(i) is in the scope of the patient-class prescriber's authority; or

(ii) involves a controlled drug;

(d) the patient-class prescriber must, when exercising the patient-class prescriber's authority in relation to medicinal cannabis, comply with any conditions imposed on a TGA approval relating to the medicinal cannabis;

(e) the patient-class prescriber must—

(i) obtain a treatment consent before exercising the patient-class prescriber's authority in relation to an eligible patient; and

(ii) keep the treatment consent;

Note—

For requirements relating to the keeping of records and information, see part 6.

(f) if an eligible patient is a driving restricted patient—the patient-class prescriber must—

(i) obtain a written driving acknowledgement from the patient before exercising the patient-class prescriber's authority in relation to the patient; and

(ii) keep the written driving acknowledgement.

Note—

For requirements relating to the keeping of records and information, see part 6.

(3) If the chief executive knows, or reasonably suspects, a patient-class prescriber has breached a condition mentioned in

subsection (2), the chief executive must give the patient-class prescriber written notice of the knowledge or suspicion.

Note—

A specialist medical practitioner is no longer a member of a class of specialist medical practitioners prescribed under section 54, and may not exercise the authority of a patient-class prescriber—

(a) while the specialist medical practitioner is breaching a condition mentioned in subsection (2)(a) or (b); or

(b) if the specialist medical practitioner has breached a condition mentioned in subsection (2)(c) to (f).

(4) In this section—

authority, of a patient-class prescriber, means the authority of the patient-class prescriber under section 53 of the Act.

driving restricted patient means a patient who—

(a) is at least 16 years old; and

(b) has capacity to consent to treatment with medicinal cannabis; and

(c) will be treated by the patient-class prescriber with medicinal cannabis containing delta-9-tetrahydrocannabinol.

treatment consent, in relation to the treatment of an eligible patient with medicinal cannabis, means a written consent to treat the patient from a person with authority to consent to treatment of the patient with medicinal cannabis.

Division 3 Restricted access patients

58 Prescribed persons—Act, s 61(7), definition *prescribed person*

(1) For section 61(7) of the Act, definition *prescribed person*, a person mentioned in column 2 is a prescribed person for the purpose of treating a patient in the care of an institution mentioned in column 1.

Column 1 Institutions	Column 2 Prescribed persons
State schools	A person who— (a) is employed by the chief executive (education) at the State school; and (b) has been authorised, in writing by the State school's principal, to administer medicinal cannabis.
Non-State schools	A person who— (a) is employed at the non-State school; and (b) has been authorised, in writing by the non-State school's principal, to administer medicinal cannabis.
QEC approved services	A person who— (a) is a staff member of the QEC approved service; and (b) has been authorised, in writing by the approved provider for the QEC approved service, to administer medicinal cannabis.
Approved education and care services	A person who— (a) is a staff member in relation to the approved education and care service; and (b) has been authorised, in writing by the approved provider for the approved education and care service, to administer medicinal cannabis.

(2) In this section—

approved education and care service means an approved education and care service under the Education and Care Services National Law (Queensland).

approved provider—

(a) in relation to an approved education and care service, see the Education and Care Services National Law (Queensland), section 5; or

(b) in relation to a QEC approved service, see the *Education and Care Services Act 2013*, schedule 1.

chief executive (education) means the chief executive of the department in which the *Education (General Provisions) Act 2006* is administered.

non-State school means an accredited school under the *Education (Accreditation of Non-State Schools) Act 2017*.

principal, of a non-State school with no position by that name, means the person responsible for the school's day-to-day management.

QEC approved service means a QEC approved service under the *Education and Care Services Act 2013*.

staff member—

(a) in relation to an approved education and care service, see the Education and Care Services National Law (Queensland), section 5; or

(b) of a QEC approved service, see the *Education and Care Services Act 2013*, schedule 1.

State school means a state school under the *Education (General Provisions) Act 2006*.

Division 4 Authorised ways and eligible persons

Subdivision 1 Preliminary

59 Definitions for division

In this division—

authority, of an eligible person, means the authority of the eligible person to deal with medicinal cannabis under this division.

authorised hospital staff member, at a hospital, means an eligible person authorised under this division to deal with medicinal cannabis at the hospital.

hospital-dispensed medicinal cannabis means medicinal cannabis dispensed under section 67(4)(a).

patient-supplied medicinal cannabis, in relation to a relevant patient, means medicinal cannabis that is—

(a) lawfully obtained by—

(i) the patient; or

(ii) a carer, or another person authorised to obtain and possess medicinal cannabis, for the patient; and

(b) supplied by a person mentioned in paragraph (a) to an authorised hospital staff member for the purpose of treating the patient while the patient is at a hospital.

relevant patient means a person who—

(a) is a patient, other than an outpatient, being treated at a hospital; and

(b) is—

(i) a patient being treated by a patient-class prescriber under section 53 of the Act; or

(ii) a patient being treated under a medicinal cannabis approval; or

(iii) a patient being treated under a clinical trial approval.

60 Eligible persons and authorised ways—Act, s 68

(1) The following persons are prescribed as eligible persons for section 68(3) of the Act, definition *eligible person*, paragraph (c)—

(a) pharmacy technicians;

(b) state analysts and trainee state analysts.

Note—

Health practitioners, including doctors, enrolled nurses, pharmacists and registered nurses, are eligible persons under section 68(3) of the Act, definition *eligible person*, paragraph (a).

(2) For section 68(1)(a) of the Act, a way in which a class of eligible person may, under this division, deal with medicinal cannabis is prescribed as an authorised way for the class of eligible person.

Subdivision 2 Hospital staff

61 Dosage conditions do not apply to authorised hospital staff members

(1) A dosage condition for a relevant patient does not apply to an authorised hospital staff member.

(2) In this section—

dosage condition, for a relevant patient, means a condition, relating to the dosage of medicinal cannabis that may be prescribed for or used by the patient—

(a) stated in a medicinal cannabis approval or clinical trial approval; or

(b) imposed under section 34(2), 35(2) or 52(1)(b) of the Act.

62 Authority ends when relevant patient leaves hospital

An authorised hospital staff member at a hospital only has authority, in relation to a relevant patient, while the relevant patient is being treated at the hospital.

63 Use of patient-supplied medicinal cannabis

(1) This section applies to the patient-supplied medicinal cannabis of a relevant patient.

(2) Nothing in this division authorises an authorised hospital staff member to deal with the patient-supplied medicinal cannabis in a way that causes the patient-supplied medicinal cannabis to be used to treat a patient other than the relevant patient.

(3) When the relevant patient leaves the hospital, an authorised hospital staff member is authorised to issue or supply the patient's patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis to—

(a) the patient; or

(b) a carer, or another person authorised to obtain and possess medicinal cannabis, for the patient.

64 Hospital doctors

(1) This section applies if—

(a) a doctor is employed or contracted to practise medicine at a hospital; and

(b) a relevant patient is being treated at the hospital.

(2) To the extent necessary to practise medicine at the hospital, the doctor is authorised to do the following—

(a) obtain patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis when at the

hospital for the purpose of treating the patient at the hospital;

(b) possess the medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital;

(c) if the doctor is reasonably satisfied the patient needs the medicinal cannabis for a therapeutic use as part of the patient's medical treatment at the hospital—

(i) issue the medicinal cannabis to an authorised hospital staff member at the hospital who is treating the patient; or

(ii) administer the medicinal cannabis to the patient at the hospital;

(d) give an authorised hospital staff member at the hospital an oral or written instruction to administer the medicinal cannabis to the patient at the hospital.

65 Enrolled nurses

(1) This section applies if—

(a) an enrolled nurse is employed or contracted to practise nursing at a hospital; and

(b) a relevant patient is being treated at the hospital.

(2) To the extent necessary to practise nursing at the hospital, the enrolled nurse is authorised to do the following—

(a) possess patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital;

(b) administer the medicinal cannabis to the patient at the hospital—

(i) in accordance with a written instruction of a doctor employed or contracted to practise medicine at the hospital; and

(ii) under the personal supervision of a doctor employed or contracted to practise medicine at the hospital or a registered nurse employed or contracted to practise nursing at the hospital.

(3) Subsection (2) does not apply if the registration of the enrolled nurse under the Health Practitioner Regulation National Law is subject to a condition that the enrolled nurse is not qualified to administer controlled drugs.

66 Registered nurses

(1) This section applies if—

(a) a registered nurse is employed or contracted to practise nursing at a hospital; and

(b) a relevant patient is being treated at the hospital.

(2) To the extent necessary to practise nursing at the hospital, the registered nurse is authorised to do the following—

(a) possess patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital;

(b) administer the medicinal cannabis to the patient at the hospital in accordance with an oral or written instruction of a doctor employed or contracted to practise medicine at the hospital.

67 Pharmacists

(1) Subsections (2) to (4) apply to a pharmacist practising pharmacy at a hospital.

(2) The pharmacist is authorised to obtain patient-supplied medicinal cannabis, and possess the medicinal cannabis at the pharmacist's dispensary, if the pharmacist is obtaining and possessing the medicinal cannabis for the purpose of issuing the medicinal cannabis to an authorised hospital staff member

at the hospital for the treatment of a relevant patient at the hospital.

(3) The pharmacist is authorised to obtain medicinal cannabis that is not patient-supplied medicinal cannabis, and possess the medicinal cannabis at the pharmacist's dispensary, if the pharmacist is obtaining and possessing the medicinal cannabis for the purpose of dispensing the medicinal cannabis to the following persons for the purpose of treating a relevant patient at the hospital—

(a) the patient;

(b) a carer, or another person authorised to obtain and possess medicinal cannabis, for the patient.

(4) The pharmacist is authorised to—

(a) dispense medicinal cannabis mentioned in subsection (3) (***hospital-dispensed medicinal cannabis***) to the following persons for the purpose of treating the patient at the hospital—

(i) the patient;

(ii) a carer, or another person authorised to obtain and possess medicinal cannabis, for the patient; and

(b) issue patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis to an authorised hospital staff member at the hospital—

(i) in accordance with the oral or written instruction of a doctor employed or contracted to practise medicine at the hospital; and

(ii) for the purpose of treating a relevant patient at the hospital.

(5) If there is no pharmacist practising pharmacy at a hospital, a doctor employed or contracted to practise medicine at the hospital may exercise the authority of a pharmacist under subsections (3) and (4)(a) at—

(a) a hospital pharmacy at the hospital; or

(b) if the hospital does not have a hospital pharmacy—the place where medicinal cannabis is stored at the hospital.

68 Pharmacy technicians

To the extent necessary to perform the duties of a pharmacy technician at a hospital, a pharmacy technician is authorised to do the following under the personal supervision of a pharmacist present at the hospital—

(a) possess medicinal cannabis mentioned in section 67(2) and (3) at the hospital;

(b) issue patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis to an authorised hospital staff member at the hospital—

(i) in accordance with the oral or written instruction of a doctor employed or contracted to practise medicine at the hospital; and

(ii) for the purpose of treating a relevant patient at the hospital.

Subdivision 3 State analysts and trainee State analysts

69 Manufacture of medicinal cannabis

(1) To the extent necessary to perform a State analyst's official duties, a State analyst is authorised to manufacture medicinal cannabis.

(2) A trainee State analyst under the personal supervision of a State analyst is authorised to manufacture medicinal cannabis.

Division 5 Offences

70 Misuse of written instruction for medicinal cannabis

(1) A person must not give, or purport to give, a written instruction for medicinal cannabis unless the person is authorised, under this regulation, to give the written instruction.

Maximum penalty—20 penalty units.

(2) A person who is authorised, under this regulation, to give a written instruction for medicinal cannabis must not prepare a written instruction for medicinal cannabis in the person's own name unless the person has a reasonable excuse.

Maximum penalty—20 penalty units.

71 Unsafe disposal or use of medicinal cannabis

(1) A person must not destroy, or otherwise dispose of or use, medicinal cannabis in a way that—

(a) endangers the life or safety of a person or domestic animal; or

(b) exposes food, drink, a condiment, a drug or a poison to the risk of contamination by the medicinal cannabis; or

(c) allows access to medicinal cannabis to someone not authorised to possess it.

Maximum penalty—20 penalty units.

(2) In this section—

poison see the *Health Act 1937*, section 5.

Division 6 Medicinal cannabis management plans

72 Additional matters to be dealt with in medicinal cannabis management plans—Act s 70(4)

For section 70(4) of the Act, a medicinal cannabis management plan, made by a person required to comply with the security standard under section 124, must state how the person will store the medicinal cannabis in a way that complies with the security standard.

Note—

See section 71 of the Act for who must make a medicinal cannabis management plan.

Part 4 Lawful directions

Division 1 Lawful directions generally

73 Preventing fraudulent lawful directions

A prescriber must take reasonable steps to prevent another person from fraudulently creating or changing a lawful direction, using the prescriber's system for creating and managing lawful directions.

Maximum penalty—20 penalty units.

Division 2 Prescriptions

Subdivision 1 Prescriptions generally

74 Prescriptions for medicinal cannabis

A prescriber, when prescribing medicinal cannabis, must comply with this division.

Maximum penalty—20 penalty units.

75 Form of prescriptions

A prescription must—

(a) be signed by the prescriber; and

(b) be legible; and

(c) use terms or symbols used in the ordinary practice of the prescriber's profession; and

(d) if the prescription is amended or corrected—use terms or symbols to show the amendment or correction is made by the prescriber.

76 Content of prescriptions

(1) A prescription must include the following information—

(a) the prescriber's name;

(b) the place where the prescriber usually practices the prescriber's profession;

(c) the prescriber's telephone number or pager number;

(d) the prescriber's professional qualification and prescriber number;

(e) the date of the prescription;

(f) if the prescription is made in accordance with a medicinal cannabis approval—the name and address of the dispensing pharmacy for the approval;

(g) the name, address and date of birth of the person for whom the medicinal cannabis is prescribed;

(h) the name, type, form and strength of the medicinal cannabis to be dispensed;

(i) the quantity of the medicinal cannabis to be dispensed, described in both words and numbers;

(j) adequate instructions about using the medicinal cannabis;

(k) the dose to be taken or administered and if more than 1 item is prescribed the dose to be taken or administered for each item.

(2) However, the information mentioned in subsection (1)(b), (d) and (i) is not required to be included in the prescription if the information is—

(a) contained in a person's medication chart entry while the person is being treated in a hospital; or

(b) entered into a person's national medication chart prescription.

(3) Subject to subsection (4), the prescription must not prescribe more than 1 item.

(4) The prescription may prescribe more than 1 item if each item is for medicinal cannabis, including different types or forms of medicinal cannabis.

(5) The prescription must not allow for medicinal cannabis to be dispensed in accordance with the prescription on more than 1 occasion.

(6) In this section—

medication chart entry means a written entry—

(a) in a chart, record or system for a place; and

(b) stating medicines that may be supplied, issued or administered as a treatment dose to a person being treated at the place.

national medication chart prescription has the same meaning as a medication chart prescription under the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth), section 19AA.

prescriber number means the number allotted, under section 8A of the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth), to a prescriber's approval under section 92 of the *National Health Act 1953* (Cwlth).

Subdivision 2 Paper prescriptions

77 Paper prescriptions generated by computer

A computer-generated paper prescription must be generated in a way that complies with schedule 1.

78 Electronic communication of paper prescriptions

(1) A prescriber may provide a paper prescription to a dispenser using electronic communication.

Examples of ways paper prescriptions may be provided using electronic communication—

facsimile or email

(2) The prescriber must—

(a) telephone the dispenser and confirm the details of the paper prescription within 24 hours of sending the prescription using electronic communication; and

(b) provide the paper prescription to the dispenser within 7 days of sending the prescription using electronic communication.

Subdivision 3 Electronic prescriptions

79 Electronic prescriptions

(1) A prescriber must not use electronic prescriptions unless the prescriber's system for recording the electronic prescriptions has the following features—

(a) information in an electronic prescription is securely sent to a dispenser;

(b) information in an electronic prescription is not disclosed to a person who is not authorised to see the information;

(c) the prescriber's signature is shown for each electronic prescription;

(d) any change or amendment to an electronic prescription is identifiable;

(e) the same information is shown for an electronic prescription when it is viewed by the prescriber and dispenser;

(f) access to the system is controlled using security measures to prevent a person who is not authorised to access the system from creating an electronic prescription.

(2) For subsection (1)(c), the prescriber's signature must be created and shown in a way that ensures the signature—

(a) uniquely identifies the prescriber; and

(b) can only be made by the prescriber; and

(c) is only connected to electronic prescriptions made by the prescriber.

Part 5 Dispensing medicinal cannabis

Division 1 Packaging and labelling

80 Packaging

(1) A person authorised to issue, supply or sell medicinal cannabis must not issue, supply or sell medicinal cannabis to another person unless the way it is packaged complies with part 2 of the current Poisons Standard.

Maximum penalty—20 penalty units.

(2) The person is taken to have complied with subsection (1) if the medicinal cannabis is packaged in a way that complies with another law of the State or Commonwealth stating requirements for the packaging of medicinal cannabis.

81 Labelling generally

(1) A person authorised to issue, supply or sell medicinal cannabis must not issue, supply or sell medicinal cannabis to another person unless the package containing the medicinal cannabis bears a label that complies with part 2 of the current Poisons Standard.

Maximum penalty—20 penalty units.

(2) The person is taken to have complied with subsection (1) if the label complies with another law of the State or Commonwealth stating requirements for the labelling of medicinal cannabis.

82 Labelling by pharmacist

(1) This section applies to a pharmacist who dispenses medicinal cannabis.

(2) The pharmacist must attach a label, stating the following information, to the manufacturer's package of the medicinal

cannabis, ensuring the label does not obscure the instructions for the use of the medicinal cannabis—

(a) the name of the prescriber who gave the lawful direction for the medicinal cannabis;

(b) the initials of the pharmacist;

(c) the name and business address of the pharmacist's dispensary;

(d) the name of the person to be treated with the medicinal cannabis;

(e) the date the medicinal cannabis is dispensed;

(f) the name of the medicinal cannabis used by the prescriber in the lawful direction;

(g) the strength of, and the quantity or volume of, the medicinal cannabis;

(h) directions about the use of the medicinal cannabis;

(i) if the expiry date of the medicinal cannabis is not visible—the expiry date.

Maximum penalty—20 penalty units.

83 Labelling by single-patient prescribers and patient-class prescribers

(1) This section applies to a single-patient prescriber or a patient-class prescriber (the ***doctor***) who issues or supplies medicinal cannabis.

(2) The doctor must attach a label, stating the following information, to the manufacturer's package of the medicinal cannabis, ensuring the label does not obscure the instructions for the use of the medicinal cannabis—

(a) the name of the doctor;

(b) the name and address of the business or entity in relation to which the doctor practices medicine;

(c) the name of the person to be treated with the medicinal cannabis;

(d) the date the medicinal cannabis is issued or supplied;

(e) the name, used by the doctor, for the medicinal cannabis;

(f) the strength of, and the quantity or volume of, the medicinal cannabis;

(g) directions about the use of the medicinal cannabis;

(h) if the expiry date of the medicinal cannabis is not visible—the expiry date.

Maximum penalty—20 penalty units.

84 Warnings to be printed on labels

(1) A person required to attach a label to a manufacturer's package under section 82 or 83 must also ensure the label has the following warnings printed on it—

(a) 'Keep out of reach of children';

(b) 'This medication may cause drowsiness and may increase the effects of alcohol';

(c) for medicinal cannabis containing delta-9-tetrahydrocannabinol, whether or not the medicinal cannabis also contains cannabidiol—'Do not drive a motor vehicle or operate machinery while taking this medication'.

Maximum penalty—20 penalty units.

(2) However, a warning mentioned in subsection (1) does not need to be printed on the label if the warning—

(a) appears on the manufacturer's package; and

(b) is clearly visible after the label is attached to the manufacturer's package.

85 Chief executive may approve alternative packaging or labelling

(1) The chief executive may, on application or on the chief executive's own initiative, approve a way (an ***alternative way***) of packaging or labelling medicinal cannabis.

(2) The chief executive must only approve an alternative way if the chief executive is reasonably satisfied the alternative way is as safe as the packaging or labelling requirements for medicinal cannabis under the current Poisons Standard.

(3) The approval may be subject to conditions and apply to—

(a) a stated person packaging or labelling medicinal cannabis in a particular way; or

(b) a stated type or form of medicinal cannabis.

(4) If the approval applies to a stated type or form of medicinal cannabis, the approval must be published on the department's website.

(5) In a proceeding against a person for an offence against sections 80 to 84, it is a defence for the person to show that—

(a) for an offence against section 80—the way in which the person packaged the medicinal cannabis was in accordance with an approval under this section; or

(b) for an offence against sections 81 to 84—the way in which the person labelled the medicinal cannabis was in accordance with an approval under this section.

86 Restriction on using contaminated packages

A person must not use a package to hold medicinal cannabis if the person has used the package, or knows the package has been used, to hold any substance or thing likely to contaminate or affect the quality or taste of the medicinal cannabis if the medicinal cannabis is put in the package.

Maximum penalty—20 penalty units.

87 Restriction on selling in second-hand packages

(1) This section applies to a person packaging medicinal cannabis for sale.

(2) The person must not use a package the person has previously used or knows has been previously used.

Maximum penalty—20 penalty units.

Division 2 Dispensing

88 When medicinal cannabis must not be dispensed

(1) This section applies if a dispenser is asked to dispense medicinal cannabis on a prescription.

(2) The dispenser must not dispense the medicinal cannabis if the medicinal cannabis appears to have been prescribed more than 3 months before the date the prescription is presented to the dispenser.

Maximum penalty—20 penalty units.

89 Dealing with prescriptions

(1) This section applies to a dispenser who dispenses medicinal cannabis on a prescription.

(2) The dispenser must, when dispensing the medicinal cannabis, annotate the prescription (the ***annotated prescription***) with the following information—

(a) a statement that the prescription has been dispensed;

(b) the date;

(c) the name or initials of the dispenser;

(d) the name and address of the dispenser's dispensary.

Maximum penalty—20 penalty units.

(3) The dispenser must send the chief executive—

(a) for a paper prescription—a copy of the annotated prescription—

(i) in paper form; or

(ii) in an approved electronic form by electronic means; or

(b) for an electronic prescription—the annotated prescription by electronic means.

(4) The dispenser must comply with subsection (3) within 72 hours after dispensing the medicinal cannabis.

Maximum penalty—20 penalty units.

(5) The dispenser must keep a paper prescription in paper form.

Maximum penalty—20 penalty units.

Note—

For requirements relating to the keeping of records and information, see part 6.

(6) In this section—

annotate, a prescription with information, means—

(a) for a paper prescription—legibly and permanently indicate the information on the prescription; or

(b) for an electronic prescription—enter the information in the prescription.

90 Issuing, selling or supplying medicinal cannabis after expiry date

A person must not issue, sell or supply medicinal cannabis after the expiry date for the medicinal cannabis stated on the manufacturer's package for the medicinal cannabis or a label attached to the manufacturer's package.

Maximum penalty—20 penalty units.

Division 3 Advertising medicinal cannabis

91 Advertising medicinal cannabis

(1) A person must not advertise, or cause someone else to advertise, a substance that is or contains medicinal cannabis, whether or not the medicinal cannabis is named in the advertisement.

Maximum penalty—20 penalty units.

(2) Subsection (1) does not apply to—

(a) an advertisement in a professional or trade journal; or

(b) a price list, advertisement or promotional material intended for circulation only to the wholesale drug trade or medical or pharmaceutical professions.

(3) In this section—

advertise, medicinal cannabis, means the use of an oral or written statement, pictorial representation or design, in any way that is intended to promote, whether directly or indirectly, the administration, issue, prescription, sale, supply or use of medicinal cannabis.

Part 6 Record-keeping

Division 1 Record-keeping generally

92 Records may be made and kept electronically

A person required to make or keep a record under a provision of the Act or this regulation may make or keep the record electronically, unless the provision expressly states otherwise.

93 Recording information on paper

(1) This section applies if a person writes information on a paper document to comply with a requirement under a provision of the Act or this regulation.

(2) The information must be—

(a) written legibly in ink; and

(b) durably marked on the paper.

Maximum penalty—20 penalty units.

(3) However, the person's signature need not be legible.

94 Keeping information

(1) This section applies to a person responsible for controlling the recording and keeping of information to comply with a requirement under a provision of the Act or this regulation.

(2) The person must ensure the information—

(a) is readily retrievable; and

(b) cannot be altered, obliterated, deleted or removed, without detection; and

(c) is kept for a period of 2 years after the date the information is recorded.

Maximum penalty—20 penalty units.

95 Record to be made on day of transaction

If, under a provision of the Act or this regulation, a person must enter details of a transaction involving medicinal cannabis in a document, the person must make the entry on the day of the transaction, unless the provision expressly states otherwise.

Maximum penalty—20 penalty units.

96 Stocktake

(1) A person required, under the Act or this regulation, to make or keep a record (the ***record***) relating to the amount of medicinal cannabis that is possessed by the person, or otherwise kept, at a place, must do the following (a ***stocktake***) at the times stated in subsection (2)—

(a) find out the quantity or volume of each type and form of medicinal cannabis possessed by the person or kept at the place;

(b) enter the quantity or volume of each type and form of medicinal cannabis possessed by the person or kept at the place in the appropriate part of the record and—

(i) if the record is kept in a book—sign and date each entry; and

(ii) if the record is kept in another form—show the person's name and the date of the entry.

Maximum penalty—20 penalty units.

(2) The person must do a stocktake—

(a) if the person becomes responsible for possessing medicinal cannabis at the place, or monitoring medicinal cannabis kept at the place, for a 7-day period or longer—immediately after becoming responsible; and

(b) at monthly intervals.

97 Discrepancy to be immediately reported to chief executive

(1) This section applies to a person who, under the Act or this regulation, is required to keep or update a record book, keep or update records or ensure records are kept (the ***records***), about transactions involving medicinal cannabis and who—

(a) finds a discrepancy between—

(i) the actual quantity or volume of a type or form of medicinal cannabis to which the record relates; and

(ii) the quantity or volume of the type or form of medicinal cannabis stated in the record; or

(b) knows, or reasonably suspects, the medicinal cannabis has been lost, misappropriated or stolen.

(2) The person must immediately give the chief executive a written notice about the discrepancy, loss, misappropriation or theft.

Maximum penalty—20 penalty units.

98 Records not to be changed but may be corrected

(1) A person must not cancel, change or obliterate an entry made in a book or other record kept under the Act or this regulation.

Maximum penalty—20 penalty units.

(2) However, the person who made the entry may correct the entry by a signed and dated marginal note or footnote giving the correct details.

99 False, misleading or incomplete entries

A person must not make an entry in a book or record required to be kept under the Act or this regulation if the person knows the entry is false, misleading or incomplete.

Maximum penalty—20 penalty units.

Division 2 Record-keeping by particular doctors

100 Particular doctors to record transactions involving medicinal cannabis

(1) This section applies to a doctor other than a doctor employed or contracted to practise medicine at a hospital or a nursing home.

Note—

For record-keeping requirements relating to hospitals and nursing homes, see division 5.

(2) A doctor must record transactions involving medicinal cannabis in the doctor's record book in the way required under this section.

Maximum penalty—20 penalty units.

(3) The doctor must—

(a) use a separate record book, or a separate part of the record book, for—

(i) if the medicinal cannabis is possessed by the doctor for the purpose of treating particular patients—each patient; or

(ii) otherwise—each type of medicinal cannabis; and

(b) enter in the book full details of each transaction involving medicinal cannabis administered, obtained, supplied, issued or otherwise used by the doctor; and

(c) make the entry as soon as practicable after, and on the day of, the transaction.

(4) The doctor must include the following details in the entry—

(a) the date of the transaction;

(b) a description of the nature of the transaction;

(c) the quantity or volume of the medicinal cannabis involved in the transaction;

(d) if the medicinal cannabis is obtained by the doctor, who is a patient-class prescriber or single-patient prescriber, under section 53(2) or 57(2) of the Act—

(i) the name and address of the person (the ***provider***) who sold or otherwise provided the medicinal cannabis to the doctor; and

(ii) the provider's invoice number, if any;

(e) if the doctor issues or supplies the medicinal cannabis to a person—

(i) the name and address of the person; and

(ii) the name of the person who made the lawful direction or the oral or written instruction in accordance with which the medicinal cannabis was issued or supplied; and

(iii) if the doctor is a patient-class prescriber or single-patient prescriber who possessed the medicinal cannabis under section 53(2) or 57(2) of the Act—the balance of the medicinal cannabis possessed by the doctor after the transaction;

(f) if the doctor administers the medicinal cannabis—

(i) the name and address of the person to whom the medicinal cannabis was administered; and

(ii) the person who made the lawful direction or the oral or written instruction in accordance with which the medicinal cannabis was administered; and

(iii) if the doctor is a single-patient prescriber or patient-class prescriber who possessed the medicinal cannabis under section 53(2) or 57(2) of the Act—the balance of the medicinal cannabis possessed by the doctor after the transaction.

(5) In this section—

record book means a record book mentioned in the *Health (Drugs and Poisons) Regulation 1996*, section 111(1).

Division 3 Record-keeping by pharmacists

101 Definition for division

In this division—

controlled drugs record see the *Health (Drugs and Poisons) Regulation 1996*, section 86.

102 Pharmacists to record transactions involving medicinal cannabis in controlled drugs record

(1) A pharmacist must personally record transactions involving medicinal cannabis in the controlled drugs record for the pharmacist's dispensary in the way required under this section and section 103.

Maximum penalty—20 penalty units.

(2) The pharmacist must use a separate controlled drugs record, or a separate part of the controlled drugs record, for—

(a) if the medicinal cannabis is possessed by the pharmacist for the purpose of treating particular patients—each patient; or

(b) otherwise—each type of medicinal cannabis.

(3) Each page or part of the controlled drugs record relating to medicinal cannabis must have a heading stating the following—

(a) the measurement unit in which quantities of medicinal cannabis involved in a transaction are recorded;

(b) for a record kept under subsection (2)(a)—the name of the patient to whom the record relates;

(c) for a record kept under subsection (2)(b)—the type of medicinal cannabis to which the record relates.

(4) If the pharmacist starts a new controlled drugs record, the pharmacist must check the stock of medicinal cannabis at the pharmacist's dispensary and record in the controlled drugs record—

(a) the stock of medicinal cannabis held when the record is started; and

(b) a reference to the most recent entry in the previous record about—

(i) if medicinal cannabis is possessed by the pharmacist for the purpose of treating a particular patient—medicinal cannabis possessed for the patient; or

(ii) otherwise—the particular type of medicinal cannabis.

(5) If the pharmacist, after dispensing, supplying or issuing medicinal cannabis, makes an entry on a page or part of the controlled drugs record on which there is no other entry, the pharmacist must record, as the first entry on the page or part—

(a) the quantity or volume of—

(i) if the medicinal cannabis was possessed by the pharmacist for the purpose of treating a particular patient—medicinal cannabis that was possessed by the pharmacist for the purpose of treating the patient before the transaction; or

(ii) otherwise—the type of medicinal cannabis that was possessed by the pharmacist before the transaction; and

(b) a reference to the most recent entry about the medicinal cannabis.

103 Entries to be made in controlled drugs record

(1) If there is more than 1 transaction on a day, the pharmacist must enter the details of each transaction in the controlled drugs record in the order in which the transactions happen.

(2) The pharmacist must include the following details for each entry—

(a) the date of the transaction;

(b) a description of the nature of the transaction;

(c) the quantity or volume of the medicinal cannabis involved in the transaction;

(d) if the medicinal cannabis is obtained by the pharmacist—

(i) the name and address of the person (the ***provider***) who sold or otherwise provided the medicinal cannabis to the pharmacist; and

(ii) the provider's invoice number, if any;

(e) if the medicinal cannabis is dispensed—

(i) the name and address of the person to, or for whom, the medicinal cannabis was dispensed; and

(ii) the name of the person who made the lawful direction or the oral or written instruction in accordance with which the medicinal cannabis was dispensed; and

(iii) the balance of the medicinal cannabis in stock at the dispensary after the transaction.

(3) The pharmacist must—

(a) for a controlled drugs record kept in a book—initial each line of the entry; or

(b) for a controlled drugs record kept in another form—include the pharmacist's initials on each line of the entry.

104 Pharmacist to keep documents

A pharmacist must keep all documents relating to medicinal cannabis dispensed by the pharmacist.

Maximum penalty—20 penalty units.

Division 4 Record-keeping by wholesalers

105 Records of transactions to be kept by wholesalers

(1) A wholesaler must keep, in the way required under subsections (2) to (4), a record of transactions that are the wholesale of medicinal cannabis (a ***wholesaler's register***)—

(a) as written entries in a book; or

(b) in an electronic form; or

(c) in another way approved by the chief executive.

Maximum penalty—20 penalty units.

(2) If the wholesaler's register is a book, the wholesaler must ensure each page of the register—

(a) has a heading describing the type and form of medicinal cannabis involved in a transaction and the measurement unit in which quantities of the medicinal cannabis are recorded; and

(b) is ruled into columns with headings describing the nature of the details to be recorded in each column.

(3) If the wholesaler's register is in an electronic form, the wholesaler must ensure the entries in the register are stored in a computer system that has enough capacity and backup capability for the purpose.

(4) The wholesaler must—

(a) use a separate page, or a separate part of the wholesaler's register, for each type of medicinal cannabis; and

(b) enter in the register the following details of each transaction—

(i) the date of the transaction;

(ii) the name and address of the person to, or for, whom the medicinal cannabis was sold;

(iii) the invoice or other number of the transaction;

(iv) the quantity or volume of medicinal cannabis sold;

(v) the balance of medicinal cannabis in stock at the wholesaler's premises after the transaction; and

(c) ensure each transaction is recorded in the order in which it happens.

(5) The wholesaler must keep the wholesaler's register at the wholesaler's business premises.

(6) If the wholesaler has more than 1 wholesaling approval and the wholesaler's records are kept on a computer at the wholesaler's central or main office, the wholesaler must keep the records for each approval at the premises used for wholesaling the medicinal cannabis under the approval.

(7) If the wholesaler is required, under the *Health (Drugs and Poisons) Regulation 1996*, section 50, to keep a controlled drugs register for controlled drugs sold by the wholesaler, the wholesaler must comply with subsection (1) by ensuring the transactions mentioned in that subsection are recorded in the controlled drugs register.

Division 5 Record-keeping by hospitals and nursing homes

Subdivision 1 Preliminary

106 Definitions for division

In this division—

central storage point, in relation to a hospital or nursing home, means the place where medicinal cannabis is stored until the medicinal cannabis is transferred to a unit of the hospital or nursing home for administration to a person in the care of the hospital or nursing home.

central storer means the person in charge of medicinal cannabis at a hospital or nursing home if medicinal cannabis is kept at a central storage point.

main issue book, in relation to medicinal cannabis, means the book in which transactions involving the medicinal cannabis are required to be recorded under section 108.

single storage book, in relation to medicinal cannabis, means the book in which transactions involving the medicinal cannabis are required to be recorded under section 116.

single storage point, in relation to a hospital or nursing home, means the place where medicinal cannabis is stored until it is administered to a person in the care of the hospital or nursing home.

single storer means the person in charge of medicinal cannabis at a hospital or nursing home if the medicinal cannabis is kept at a single storage point until it is administered to patients at the hospital or nursing home.

unit means a ward, operating theatre or department of a hospital or nursing home.

unit storer means the person in charge of medicinal cannabis at a unit of a hospital or nursing home.

ward book, in relation to medicinal cannabis, means the book in which transactions involving the medicinal cannabis are required to be recorded under section 110.

Subdivision 2 Hospitals and nursing homes with multiple storage points

107 Application of subdivision

This subdivision applies to a hospital or nursing home that has more than 1 storage point for medicinal cannabis.

108 Main issue book

(1) The central storer must keep a record (the ***main issue book***), as a book or in another way approved by the chief executive, of the following transactions involving medicinal cannabis—

(a) the obtaining of medicinal cannabis into the central storage point;

(b) the issue of medicinal cannabis from the central storage point.

Maximum penalty—20 penalty units.

(2) If the main issue book is kept as a book, the central storer must ensure—

(a) the main issue book is bound; and

(b) a separate main issue book, or a separate part of the main issue book, is kept for—

(i) if the medicinal cannabis is stored for the purpose of treating particular patients—each patient; or

(ii) otherwise—each type of medicinal cannabis; and

(c) each page of the main issue book that relates to medicinal cannabis—

(i) is sequentially numbered; and

(ii) has a heading stating the following—

(A) the measurement unit in which quantities of medicinal cannabis involved in a transaction are recorded; and

(B) for a record kept under paragraph (b)(i)—the name of the patient to whom the record relates; and

(C) for a record kept under paragraph (b)(ii)—the type of medicinal cannabis to which the record relates.

Maximum penalty—20 penalty units.

(3) If a person is required, under the *Health (Drugs and Poisons) Regulation 1996*, section 99, to keep a main issue book for controlled drugs at the hospital or nursing home, the central storer must comply with subsection (1) by ensuring the transactions mentioned in that subsection are recorded in the main issue book for controlled drugs.

(4) Entries about the return of medicinal cannabis to the central storer, for the purpose of destruction or disposal by a person authorised to destroy or otherwise dispose of medicinal cannabis, may be made on a single page in the main issue book that does not comply with subsection (2)(c).

109 Details to be recorded in main issue book

(1) The central storer must record the following in the main issue book for each transaction mentioned in section 108(1)—

(a) the description and quantity or volume of the medicinal cannabis involved in the transaction;

(b) the date of the transaction;

(c) the quantity or volume of medicinal cannabis kept at the central storage point after the transaction is completed;

(d) for medicinal cannabis obtained into the central storage point—

(i) the name and address of the person from whom the medicinal cannabis was obtained; and

(ii) if the medicinal cannabis was obtained for a particular person—the person's name and address;

(e) for the issue of medicinal cannabis from the central storage point—the quantity or volume of medicinal cannabis issued.

Maximum penalty—20 penalty units.

(2) The following persons must sign the entry—

(a) the central storer;

(b) if the medicinal cannabis is issued to a unit storer for a unit—the unit storer.

Maximum penalty—20 penalty units.

110 Ward book

(1) A unit storer for a unit must keep a record (the ***ward book***), as a book or in another way approved by the chief executive, of the following transactions involving medicinal cannabis—

(a) the obtaining of medicinal cannabis into the unit from the central storage point;

(b) the administration of medicinal cannabis to persons in the unit.

Maximum penalty—20 penalty units.

(2) If the ward book is kept as a book, the unit storer must ensure—

(a) the ward book is bound; and

(b) a ward book, or a separate part of the ward book, is kept for—

(i) if the medicinal cannabis is stored for the purpose of treating particular patients—each patient; or

(ii) otherwise—each type of medicinal cannabis; and

(c) each page of the ward book that relates to medicinal cannabis—

(i) is sequentially numbered; and

(ii) has a heading stating the following—

(A) the measurement unit in which quantities of medicinal cannabis involved in a transaction are recorded;

(B) for a record kept under paragraph (b)(i)—the name of the patient to whom the record relates;

(C) for a record kept under paragraph (b)(ii)—the type of medicinal cannabis to which the record relates.

Maximum penalty—20 penalty units.

(3) If a person is required, under the *Health (Drugs and Poisons) Regulation 1996*, section 101, to keep a ward drugs book for controlled drugs at a unit, a unit storer for the unit must comply with subsection (1) by ensuring the transactions mentioned in that subsection are recorded in the ward drugs book.

111 Details to be recorded in ward book when medicinal cannabis obtained into unit

(1) A unit storer for a unit must record the following in the ward book for each transaction mentioned in section 110(1)(a)—

(a) the description and quantity or volume of the medicinal cannabis involved in the transaction;

(b) the date of the transaction.

Maximum penalty—20 penalty units.

(2) The central storer must sign the entry if the central storer is reasonably satisfied the entry is correct.

Maximum penalty—20 penalty units.

112 Details to be recorded in ward book when medicinal cannabis administered in unit

(1) A unit storer for a unit must record the following in the ward book for each transaction mentioned in section 110(1)(b)—

(a) the description and quantity or volume of the medicinal cannabis involved in the transaction;

(b) the date and time of the transaction;

(c) the name of the person to whom the medicinal cannabis was administered;

(d) the quantity or volume of medicinal cannabis remaining at the unit.

Maximum penalty—20 penalty units.

(2) The person who obtains the medicinal cannabis to administer it to someone else must sign the entry if the person is reasonably satisfied the entry is correct.

Maximum penalty—20 penalty units.

113 Transfer vouchers may be used for medicinal cannabis in certain cases

(1) This section applies if, because of the size of a hospital or nursing home, or for another reason, it is not practicable for—

(a) a unit storer to sign the main issue book; or

(b) the central storer to sign the ward book.

(2) The central storer may record the issue of medicinal cannabis from the central storage point, and the unit storer may record the obtaining of the medicinal cannabis into the unit, on a document stating the things that must be recorded in a main issue book and ward book (a ***transfer voucher***).

(3) The person issuing, and the person obtaining, the medicinal cannabis must sign the transfer voucher.

Maximum penalty—20 penalty units.

114 Main issue book and ward book as 1 book

(1) Sections 110 to 112 do not apply to unit storers at a hospital or nursing home if—

(a) the central storer at the hospital or nursing home keeps 1 book that contains the information that must be recorded in the main issue book and each ward book at the hospital or nursing home; and

(b) entries in the book are signed by the person who must sign the entries in the main issue book or ward book.

(2) If a person keeps a single book for controlled drugs under the *Health (Drugs and Poisons) Regulation 1996*, section 105, the book mentioned in subsection (1) must be the single book.

Subdivision 3 Hospitals and nursing homes with 1 storage point

115 Application of subdivision

This subdivision applies to a hospital or nursing home that has 1 storage point for medicinal cannabis.

116 Single storage book

(1) A single storer must keep a record (the ***single storage book***), as a book or in another way approved by the chief executive, of the following transactions involving medicinal cannabis—

(a) the obtaining of medicinal cannabis into the single storage point at the hospital or nursing home;

(b) the issue of medicinal cannabis from the single storage point at the hospital or nursing home.

Maximum penalty—20 penalty units.

(2) If the single storage book is kept as a book, the single storer must ensure—

(a) the single storage book is bound; and

(b) a single storage book, or a separate part of the single storage book, is kept for—

(i) if the medicinal cannabis is stored for the purpose of treating particular patients—each patient; or

(ii) otherwise—each type of medicinal cannabis; and

(c) each page of the single storage book that relates to medicinal cannabis—

(i) is sequentially numbered; and

(ii) has a heading stating the following—

(A) the measurement unit in which quantities of medicinal cannabis involved in a transaction are recorded;

(B) for a record kept under paragraph (b)(i)—the name of the patient to whom the record relates;

(C) for a record kept under paragraph (b)(ii)—the type of medicinal cannabis to which the record relates.

Maximum penalty—20 penalty units.

(3) If a person is required, under the *Health (Drugs and Poisons) Regulation 1996*, section 106, to keep a single storage book for controlled drugs at the hospital or nursing home, the single storer must comply with subsection (1) by ensuring the transactions mentioned in that subsection are recorded in the single storage book for controlled drugs.

117 Details to be recorded in single storage book when medicinal cannabis deposited

(1) A single storer must record the following in the single storage book for each transaction mentioned in section 116(1)(a)—

(a) the description and quantity or volume of the medicinal cannabis involved in the transaction;

(b) the date of the transaction;

(c) the name and address of the person from whom the medicinal cannabis was obtained;

(d) if the medicinal cannabis was obtained for a particular person—the person's name and address.

Maximum penalty—20 penalty units.

(2) The single storer must sign the entry.

Maximum penalty—20 penalty units.

118 Details to be recorded in single storage book when medicinal cannabis administered

(1) A single storer must record the following in the single storage book for each transaction mentioned in section 116(1)(b)—

(a) the description and quantity or volume of the medicinal cannabis involved in the transaction;

(b) the date and time of the transaction;

(c) the name of the person to whom the medicinal cannabis was administered;

(d) the quantity or volume of medicinal cannabis remaining at the single storage point.

Maximum penalty—20 penalty units.

(2) The person who obtains the medicinal cannabis to administer it to someone else must sign the entry if the person is reasonably satisfied the entry is correct.

Maximum penalty—20 penalty units.

Subdivision 4 Other provisions about record-keeping by hospitals and nursing homes

119 Responsibility for checking accuracy of records at hospitals and nursing homes

(1) A responsible person for, or a person otherwise in charge of, a hospital or nursing home must ensure—

(a) records are kept of all transactions involving medicinal cannabis at the hospital or nursing home; and

(b) at reasonable intervals—

(i) the stock of medicinal cannabis at the hospital or nursing home is checked to ensure the records about the medicinal cannabis on hand at the hospital or nursing home are accurate; and

(ii) all records of transactions for medicinal cannabis are inspected.

Maximum penalty—20 penalty units.

(2) The person who checks the stock of medicinal cannabis and inspects the records (the ***checker***) must—

(a) write the date and results of the inspection on the record; and

(b) immediately report any of the following to a responsible person for, or a person otherwise in charge of, the hospital or nursing home or the chief executive—

(i) a contravention of this regulation;

(ii) an apparently excessive use of medicinal cannabis;

(iii) a discrepancy between the medicinal cannabis actually in stock at the hospital or nursing home and the medicinal cannabis that should, according to the records, be in stock at the hospital or nursing home; and

(c) if the checker knows, or reasonably suspects, medicinal cannabis has been lost, misappropriated or stolen—immediately give the chief executive written notice about the loss, misappropriation or theft.

Maximum penalty—20 penalty units.

(3) The checker for a hospital or nursing home must be—

(a) a responsible person for, or a person otherwise in charge of, the hospital or nursing home; or

(b) a doctor, pharmacist, registered nurse or pharmacy technician nominated in writing by a responsible person for, or a person otherwise in charge of, the hospital or nursing home.

(4) In this section—

reasonable interval means an interval of not more than 1 month that is reasonably necessary to carry out the check and inspection under subsection (1)(b).

Part 7 Transportation and delivery of medicinal cannabis

120 Definitions for part

In this part—

buyer means a person authorised to obtain and possess medicinal cannabis.

seller means a person authorised to issue, sell or supply medicinal cannabis.

121 Sending and delivering medicinal cannabis

A seller must not deliver or send medicinal cannabis to a buyer other than in a way stated in section 122 or 123.

Maximum penalty—20 penalty units.

122 Delivery of medicinal cannabis

(1) The seller, or an adult employee of the seller, may personally deliver the medicinal cannabis to the buyer, or an adult employee of the buyer, at the seller's or buyer's premises.

(2) When the seller delivers medicinal cannabis to the buyer at the buyer's premises, the seller must obtain from the person to whom the medicinal cannabis is delivered a dated and signed acknowledgement of receipt of the medicinal cannabis.

(3) The medicinal cannabis must be delivered in a securely closed package that—

(a) is addressed to the buyer; and

(b) does not contain goods other than medicinal cannabis; and

(c) contains a packing slip or similar document that—

(i) has 'Medicinal cannabis—check carefully' printed on it in bold-faced sans serif capital letters with a face depth of at least 12.5mm; and

(ii) is placed so it is visible as soon as the package is opened.

123 Sending medicinal cannabis by carrier

(1) The seller may send the medicinal cannabis to the buyer by carrier.

(2) The medicinal cannabis must be sent in a securely closed package that—

(a) is addressed to the buyer; and

(b) does not contain goods other than medicinal cannabis; and

(c) contains a packing slip or similar document that—

(i) has 'Medicinal cannabis—check carefully' printed on it in bold-faced sans serif capital letters with a face depth of at least 12.5mm; and

(ii) is placed so it is visible as soon as the package is opened.

(3) The carrier must give the seller a signed or officially receipted document acknowledging receipt of the package for delivery to the buyer.

(4) The buyer must give the carrier a signed or officially receipted document from the buyer acknowledging the buyer's receipt of the package.

Part 8 Storage of medicinal cannabis

124 Relevant person must comply with standard

(1) A relevant person who possesses, or is otherwise responsible for storing, medicinal cannabis must ensure the medicinal cannabis is stored in the way stated in the security standard.

Maximum penalty—20 penalty units.

(2) In this section—

relevant person means each of the following persons—

(a) a single-patient prescriber;

(b) a patient-class prescriber;

(c) a pharmacist;

(d) a manufacturer;

(e) a wholesaler;

(f) a responsible person for an institution that is a hospital or nursing home.

Part 9 Notification and reporting

125 Definition for part

In this part—

treatment report, for a patient, means a written report, in the approved form, detailing the patient's ongoing response to the patient's treatment with medicinal cannabis.

126 Single-patient prescribers

A single-patient prescriber must, for each patient the single-patient prescriber is treating with medicinal cannabis, provide, to the chief executive, treatment reports for the

patient at the frequency stated in the medicinal cannabis approval applying to the patient.

Maximum penalty—20 penalty units.

127 Patient-class prescribers

(1) A patient-class prescriber must, within 7 days of giving an initial lawful direction, give notice to the chief executive in the approved form.

Maximum penalty—20 penalty units.

(2) The patient-class prescriber must, for each eligible patient the patient-class prescriber is treating with medicinal cannabis, provide, to the chief executive, treatment reports for the patient at the frequency stated in the Queensland Clinical Guidance for Medicinal Cannabis published by the chief health officer.

Note—

The Queensland Clinical Guidance for Medicinal Cannabis is available on the department's website.

Maximum penalty—20 penalty units.

(3) In this section—

initial lawful direction means the first lawful direction, given by a patient-class prescriber in relation to a particular eligible patient, relating to the treatment of the eligible patient with medicinal cannabis.

Part 10 Transitional provisions

128 Definitions for part

In this part—

controlled drug manufacturer licence means a controlled drug manufacturer licence, under the *Health (Drugs and Poisons) Regulation 1996*, that authorises, or would authorise, the holder of the licence to manufacture medicinal cannabis.

controlled drug wholesaler licence means a controlled drug wholesaler licence, under the *Health (Drugs and Poisons) Regulation 1996*, that authorises, or would authorise, the holder of the licence to sell medicinal cannabis.

129 Existing licence to manufacture medicinal cannabis

(1) This section applies if, immediately before the commencement, a person is the holder of a controlled drug manufacturer licence.

(2) The person is taken to be the holder of a manufacturing approval for the type and form of medicinal cannabis the person is authorised to manufacture under the controlled drug manufacturer licence.

130 Existing application for controlled drug manufacturer licence

(1) This section applies if—

(a) a person has applied for a controlled drug manufacturer licence; and

(b) immediately before the commencement the application has not been decided.

(2) The person is taken to have applied for (the ***deemed application***) a manufacturing approval for the type and form of medicinal cannabis stated in the application for the controlled drug manufacturer licence.

(3) The chief executive must decide the deemed application under this regulation.

131 Existing licence to wholesale medicinal cannabis

(1) This section applies if, immediately before the commencement, a person is the holder of a controlled drug wholesaler licence.

(2) The person is taken to be the holder of a wholesaling approval for the type and form of medicinal cannabis the person is authorised to sell under the controlled drug wholesaler licence.

132 Existing application for controlled drug wholesaler licence

(1) This section applies if—

(a) a person has applied for a controlled drug wholesaler licence; and

(b) immediately before the commencement the application has not been decided.

(2) The person is taken to have applied for (the ***deemed application***) a wholesaling approval for the type and form of medicinal cannabis stated in the application for the controlled drug wholesaler licence.

(3) The chief executive must decide the deemed application under this regulation.

Schedule 1 Computer-generated paper prescriptions

section 77

1 Prescription form must be preprinted

(1) A computer-generated paper prescription must be generated on a preprinted form with the particulars mentioned in section 76(1)(a) to (c) preprinted on the form.

(2) However, if the prescriber practises his or her profession in association with another prescriber, the name, address and contact telephone number of the practice at which the prescriber practises his or her profession may be preprinted on the form.

2 Only prescriber may generate prescription

The computer program used to generate a computer-generated paper prescription must allow only a prescriber to generate the prescription.

3 Requirements on generation of prescription

(1) When a computer-generated paper prescription is generated, the computer program used to generate the prescription must cause the following to appear on the prescription form—

(a) a mark or line between each item on the form;

(b) the total number of items included on the form;

(c) a unique number that allows the prescription to be associated with the person for whom it is written;

(d) the particulars mentioned in section 76(1)(a), (b) and (d).

(2) The area below the space for the prescriber's signature must be scored, hatched or marked in another way to prevent

another item being written on the form below the prescriber's signature.

4 System messages

The computer program used to generate a computer-generated paper prescription must generate a message that tells the prescriber that the prescriber must write the particulars mentioned in section 76(1)(h) to (k).

5 Particulars for computer-generated paper prescription that a computer may generate

The particulars mentioned in section 76(1)(e) and (f) may, for a computer-generated paper prescription, be generated by the computer.

Schedule 2 Dictionary

section 3

administrative action, for part 2, division 8, see section 42.

amendment application, for part 2, see section 30.

application, for part 2, see section 6.

approval, for part 2, see section 6.

approved electronic form means an electronic form approved by the chief executive.

authorised hospital staff member, for part 3, division 4, see section 59.

authority, for part 3, division 4, see section 59.

buyer, for part 7, see section 120.

central storage point, for part 6, division 5, see section 106.

central storer, for part 6, division 5, see section 106.

chief health officer means the chief health officer under the *Hospital and Health Boards Act 2011*, section 52.

computer-generated paper prescription means a paper prescription generated by a computer.

controlled drug see the *Health (Drugs and Poisons) Regulation 1996*, appendix 9.

controlled drug manufacturer licence, for part 10, see section 128.

controlled drugs record, for part 6, division 3, see section 101.

controlled drug wholesaler licence, for part 10, see section 128.

current Poisons Standard see the *Therapeutic Goods Act 1989* (Cwlth), section 52A.

dispensary, in relation to a secondary dispenser, means the pharmacy from which the secondary dispenser is authorised to dispense medicinal cannabis under section 56(3) or 58(3) of the Act.

dispenser, in relation to medicinal cannabis, means a person authorised under the Act to dispense the medicinal cannabis.

electronic communication see the *Electronic Transactions (Queensland) Act 2001*, schedule 2.

electronic means, in relation to sending a document, means sending the document—

(a) embodied in a computer disk from which the document can be reproduced; or

(b) by an electronic communication.

electronic prescription means a prescription for medicinal cannabis in an approved electronic form for transfer by electronic communication.

hospital includes—

(a) a hospice; and

(b) a medical centre at a prison.

hospital-dispensed medicinal cannabis, for part 3, division 4, see section 59.

information includes a document.

information requirement notice, for part 2, see section 6.

main issue book, for part 6, division 5, see section 106.

manufacturer see section 6.

manufacturer's package, for medicinal cannabis, means a primary package for the medicinal cannabis supplied by the manufacturer of the medicinal cannabis.

manufacturing approval see section 12.

paper prescription means a prescription for medicinal cannabis in paper form whether or not the prescription was generated by a computer or handwritten.

patient-supplied medicinal cannabis, for part 3, division 4, see section 59.

pharmacist, for sections 38 and 124, means—

(a) an approved pharmacist; or

(b) a secondary dispenser acting under section 56(3) or 58(3) of the Act.

pharmacy technician means a person who—

(a) is employed or contracted to carry out functions and activities in a hospital pharmacy, under the personal supervision of a pharmacist at the hospital, that do not require the exercise of professional judgement by a pharmacist; and

(b) has, in the reasonable opinion of a person in charge of dispensing controlled drugs at the hospital, the skills and knowledge required to perform the functions and activities mentioned in paragraph (a).

prescriber means a person authorised under the Act to prescribe medicinal cannabis.

relevant patient, for part 3, division 4, see section 59.

renewal application, for part 2, see section 34.

replacement application, for part 2, see section 32.

responsible person, for an institution, see section 61(7) of the Act.

security standard means the standard entitled Standard for Security of Medicinal Cannabis Stock published by the chief health officer.

Note—

The Standard for Security of Medicinal Cannabis Stock is available on the department's website.

seller, for part 7, see section 120.

single storage book, for part 6, division 5, see section 106.

single storage point, for part 6, division 5, see section 106.

single storer, for part 6, division 5, see section 106.

transaction, involving medicinal cannabis, means an event by which—

(a) the medicinal cannabis comes into or goes out of a person's possession; or

(b) the composition, form or strength of, or way of packaging, the medicinal cannabis is changed.

Examples of transactions—

- obtaining and possessing medicinal cannabis
- manufacturing, packaging and repackaging medicinal cannabis
- moving medicinal cannabis from one place to another (with or without a change of ownership)

treatment report, for part 9, see section 125.

unit, for part 6, division 5, see section 106.

unit storer, for part 6, division 5, see section 106.

ward book, for part 6, division 5, see section 106.

wholesale, in relation to medicinal cannabis, means selling medicinal cannabis, but does not include the sale of medicinal cannabis by—

(a) a pharmacist under section 56 or 58 of the Act; or

(b) a pharmacist under section 67.

wholesaler means the holder of a wholesaling approval.

wholesaling approval see section 15.

written driving acknowledgement means a written statement, given by a person, acknowledging that it is an offence, under section 79(2AA) of the *Transport Operations (Road Use Management) Act 1995*, for the person to drive, attempt to put in motion, or be in charge of, a motor vehicle, tram, train or vessel, while the person has delta-9-tetrahydrocannabinol present in the person's blood or saliva.

written instruction means a written direction, other than a prescription, signed by a doctor and on which the following is shown—

(a) the date of the instruction;

(b) the name and date of birth of the patient to whom the instruction relates;

(c) the name, type and form, strength and directions for use of the medicinal cannabis to which the instruction relates.

1 Index to endnotes

2 Key

Key to abbreviations in list of legislation and annotations

Key		Explanation	Key		Explanation
AIA	=	**Acts Interpretation Act 1954**	**(prev)**	=	**previously**
amd	=	**amended**	**proc**	=	**proclamation**
amdt	=	**amendment**	**prov**	=	**provision**
ch	=	**chapter**	**pt**	=	**part**
def	=	**definition**	**pubd**	=	**published**
div	=	**division**	**R[X]**	=	**Reprint No. [X]**
exp	=	**expires/expired**	**RA**	=	**Reprints Act 1992**
gaz	=	**gazette**	**reloc**	=	**relocated**
hdg	=	**heading**	**renum**	=	**renumbered**
ins	=	**inserted**	**rep**	=	**repealed**
lap	=	**lapsed**	**(retro)**	=	**retrospectively**
notfd	=	**notified**	**rv**	=	**revised version**
num	=	**numbered**	**s**	=	**section**

Key		Explanation	Key		Explanation
o in c	=	order in council	sch	=	schedule
om	=	omitted	sdiv	=	subdivision
orig	=	original	SIA	=	Statutory Instruments Act 1992
p	=	page	SIR	=	Statutory Instruments Regulation 2012
para	=	paragraph	SL	=	subordinate legislation
prec	=	preceding	sub	=	substituted
pres	=	present	unnum	=	unnumbered
prev	=	previous			

3 Table of reprints

A new reprint of the legislation is prepared by the Office of the Queensland Parliamentary Counsel each time a change to the legislation takes effect.

The notes column for this reprint gives details of any discretionary editorial powers under the **Reprints Act 1992** used by the Office of the Queensland Parliamentary Counsel in preparing it. Section 5(c) and (d) of the Act are not mentioned as they contain mandatory requirements that all amendments be included and all necessary consequential amendments be incorporated, whether of punctuation, numbering or another kind. Further details of the use of any discretionary editorial power noted in the table can be obtained by contacting the Office of the Queensland Parliamentary Counsel by telephone on 3003 9601 or email legislation.queries@oqpc.qld.gov.au.

From 29 January 2013, all Queensland reprints are dated and authorised by the Parliamentary Counsel. The previous numbering system and distinctions between printed and electronic reprints is not continued with the relevant details for historical reprints included in this table.

Current as at	Amendments included	Notes
1 March 2017	none	
1 January 2018	2017 Act No. 24	

4 List of legislation

Regulatory impact statements

For subordinate legislation that has a regulatory impact statement, specific reference to the statement is included in this list.

Explanatory notes

All subordinate legislation made on or after 1 January 2011 has an explanatory note.

Public Health (Medicinal Cannabis) Regulation 2017 SL No. 15
made by the Governor in Council on 23 February 2017
notfd <www.legislation.qld.gov.au> 24 February 2017
ss 1–2 commenced on date of notification
ss 3–4, pts 2–10, schs 1–2 commenced 1 March 2017 (see s 2)
exp 1 September 2027 (see SIA s 54)
Note—The expiry date may have changed since this reprint was published. See the latest reprint of the SIR for any change.
amending legislation—

Education (Accreditation of Non-State Schools) Act 2017 No. 24
date of assent 25 August 2017
ss 1–2 comm on date of assent
ch 7 pt 19 comm 1 January 2018 (2017 SL No. 196)

5 List of annotations

Prescribed persons—Act, s 61(7), definition *prescribed person*
s 58 amd 2017 No. 24 s 254