Public Health (Medicinal Cannabis) Regulation 2017

Explanatory notes for SL 2017 No. 15

made under the

Public Health (Medicinal Cannabis) Act 2016

General Outline

Short title

Public Health (Medicinal Cannabis) Regulation 2017

Authorising law

Section 217 of the *Public Health (Medicinal Cannabis) Act 2016*

Policy objectives and the reasons for them

The *Public Health (Medicinal Cannabis) Act 2016* (the Act) established a regulatory framework under which medicinal cannabis products may be prescribed and dispensed to patients in Queensland.

The Act provides two pathways for a patient to receive treatment with medicinal cannabis:

- under the *single-patient prescriber* pathway, a medical practitioner who believes their patient may benefit from treatment with medicinal cannabis may apply to the chief executive of Queensland Health for a medicinal cannabis approval to prescribe a medicinal cannabis product for the patient
- under the *patient-class prescriber* pathway, a regulation may state a class of specialist doctors who have an as-of-right authority to prescribe specific medicinal cannabis products for patients suffering a specific range of conditions, without the need for any additional chief executive approval.

The Act also provides for patients to access medicinal cannabis through clinical trials.

The *Public Health (Medicinal Cannabis) Regulation 2017* (the Regulation) prescribes matters to support the regulatory framework established by the Act.

Achievement of policy objectives

The Regulation prescribes matters to support the operation of the Act. In particular, the Regulation provides that:

- specialists in the fields of oncology, palliative medicine, neurology, paediatrics and haematology are specialist medical practitioners who may prescribe medicinal cannabis as a patient-class prescriber, and
- patients suffering from chemotherapy-induced nausea and vomiting; symptoms associated with terminal illness; intractable (drug resistant) epilepsy in children; and spasticity due to multiple sclerosis are classes of patients to whom a specialist medical practitioner may prescribe medicinal cannabis through the patient-class prescriber pathway.

The Regulation prescribes the standard conditions that apply to a medicinal cannabis approval, dispensing approval and clinical trial approval. These conditions include, for example, requirements to maintain a current registration under the Health Practitioner Regulation National Law and comply with any relevant Therapeutic Goods Administration approvals.

The Regulation also provides for applications for manufacturing and wholesaling approvals, record-keeping, prescriptions and storage, packaging and labelling of medicinal cannabis.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the *Public Health (Medicinal Cannabis) Act 2016.*

Inconsistency with policy objectives of other legislation

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

Alternative ways of achieving policy objectives

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

Benefits and costs of implementation

As outlined in the explanatory notes to the Public Health (Medicinal Cannabis) Bill 2016, the cost associated with implementation of the Act will be met from within existing Queensland Health resources.

Consistency with fundamental legislative principles

No issues relating to fundamental legislative principles were raised by the Office of the Queensland Parliamentary Counsel. The Regulation is thought to be consistent with fundamental legislative principles. Where the legislation subdelegates powers delegated by the Act by referring to external documents, it does so only in appropriate cases where authorised by the Act. The subdelegation of powers in the Regulation is necessary to ensure the efficient administration of the Act framework.

For example, the Regulation requires relevant persons to comply with the *Standard for Security of Medicinal Cannabis Stock*, which provides for how medicinal cannabis should be safely stored (clause 124). The Regulation also provides that patient-class prescribers must provide treatment reports for each of their patients at the frequency stated in the *Queensland Clinical Guidance for Medicinal Cannabis* (clause 127). Both of these documents are made by the Chief Health Officer and published on Queensland Health's website.

Treatment with medicinal cannabis is an emerging area of health care. It is likely that the security requirements and clinical guidance around the use of medicinal cannabis will change as new issues are identified and the evidence around the use of medicinal cannabis develops. It is therefore appropriate that these requirements do not form part of the Regulation. Referring to the Standard and the Guidance document will ensure that the security arrangements and clinical guidance for medical practitioners can be kept current, with updates made quickly by the Chief Health Officer should a new issue be identified.

The Regulation also provides that:

- a medicinal cannabis wholesaler must comply with the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*, which is available on the Therapeutic Goods Administration's website (clause 39) and
- holders of a dispensing approval must comply with the *Guidelines for Dispensing of Medicines* published by the Pharmacy Board of Australia (clause 52), which is available on the Pharmacy Board of Australia's website.

As these are external requirements of the Therapeutic Goods Administration and Pharmacy Board of Australia, it is appropriate for the Regulation to refer to these documents rather than duplicate the requirements.

To enhance the visibility of the above documents to members of the Legislative Assembly, copies of each will be tabled in the Legislative Assembly.

Consultation

A wide range of external stakeholders were invited to comment on the draft Regulation, or relevant provisions, including:

- professional associations:
  - Australian Medical Association of Queensland
  - Royal Australasian College of Physicians
  - Royal Australian College of General Practitioners
  - Australian College of Rural and Remote Medicine
  - Pharmaceutical Society of Australia
  - Pharmacy Guild of Australia
  - College of Nursing
- patient and health consumer groups:
  - Cancer Council Queensland
  - Epilepsy Queensland
  - Multiple Sclerosis Queensland
  - Palliative Care Queensland
  - Health Consumers Queensland
  - Public Health Association Australia-Queensland Branch
- Commonwealth agencies:
  - the Commonwealth Department of Health (Office of Drug Control and Therapeutic Goods Administration)
  - Australian Health Practitioner Regulation Agency
- education stakeholders
  - Queensland Catholic Education Commission
  - Independent Schools Queensland.

In addition, early childhood education and care providers, including the Australian Childcare Alliance-Queensland, C&K and Goodstart Early Learning, were consulted on the Regulation at a forum of providers held in December 2016.

Hospital and Health Services were also invited to comment on the draft Regulation.

No significant issues were raised by stakeholders. Feedback received prior to finalisation of the Regulation is reflected in the Regulation or explanatory material where appropriate.

Notes on provisions

Part 1 Introduction

Division 1 Preliminary

Short title

Clause 1 provides the short title of the regulation.

Commencement

Clause 2 provides that the regulation commences on 1 March 2017.

Definitions

Clause 3 provides that definitions for the regulation are in the dictionary in schedule 2.

Division 2 General provisions

Compliance with code, guideline, protocol or standard

Clause 4 applies if a person must comply with a requirement of a code, guideline, protocol or standard; or a standard states a way of complying with a requirement of the regulation.

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

In a proceeding against a person for an offence relating to the provision, clause 4 also provides that it is a defence for the person to show that the person complied with the inconsistent requirement.

Language of documents

Clause 5 provides that a person required to give, issue or keep a document under the regulation must write the document in English. However, the document may also be written in another language if it is reasonably necessary to ensure a person named in the document understands any instructions given in the document. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Part 2 Manufacturing approvals and wholesaling approvals

Division 1 Preliminary

Definitions for part

Clause 6 provides the definitions for part 2 of the regulation.

Consistency with Commonwealth law

Clause 7 provides that part 2 applies to the manufacture of medicinal cannabis only to the extent it is consistent with Commonwealth law.

Evidentiary aids

Clause 8 provides that a certificate purporting to be signed by the chief executive stating one of a range of matters is evidence of the matter.

Division 2 Application for approvals

Subdivision 1 Preliminary

Suitability of person to hold approval

Clause 9 prescribes the matters the chief executive may have regard to, and may make inquiries about, in deciding whether a person is a suitable person to hold, or to continue to hold, a manufacturing or wholesaling approval. However, clause 9 also provides that the matters to which the chief executive may have regard in considering the suitability of the person to hold an approval are not limited to those prescribed.

Approved form

Clause 10 provides that an application for a manufacturing or wholesaling approval must be in the approved form, if there is one.

Subdivision 2 Particular provisions for application for manufacturing approval

Purpose of subdivision

Clause 11 provides that subdivision 2 sets out matters relating to applications for manufacturing approvals.

Who may apply for manufacturing approval

Clause 12 provides that a person may apply for an approval to manufacture medicinal cannabis (a *manufacturing approval*).

Criteria for grant or renewal of manufacturing approval

Clause 13 prescribes the matters that the chief executive may consider when considering an application for the grant or renewal of a manufacturing approval. Clause 13 also provides that the chief executive may grant a manufacturing approval only if satisfied that:

- the applicant is a suitable person to hold the approval
- the applicant intends to carry on a business as a manufacturer of medicinal cannabis

- 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 expertise necessary to effectively supervise the manufacture, and
- the premises used, or to be used, to manufacture the medicinal cannabis are suitable for that purpose.

Subdivision 3 Particular provisions for application for wholesaling approval

Purpose of subdivision

Clause 14 provides that the purpose of subdivision 3 is to state particular matters relating to applications for wholesaling approvals.

Who may apply for wholesaling approval

Clause 15 provides that a person may apply for an approval (a *wholesaling approval*) to wholesale medicinal cannabis to the following persons mentioned in clause 38(1)(b):

- a single-patient prescriber
- a patient-class prescriber
- a pharmacist, or
- someone in another State who may obtain the medicinal cannabis under the law of the other State.

Criteria for grant or renewal of wholesaling approval

Clause 16 prescribes the matters that the chief executive may consider when considering an application for the grant or renewal of a wholesaling approval. Clause 16 also provides that the chief executive may grant a wholesaling approval only if satisfied that:

- the applicant is a suitable person to hold the approval
- the applicant intends to carry on business as a wholesaler of medicinal cannabis, and
- the premises used, or to be used, for wholesaling the medicinal cannabis are suitable for that purpose.

Subdivision 4 Process for deciding applications

Decision on application for approval

Clause 17 prescribes requirements for making a decision on applications relating to a wholesaling approval or manufacturing approval. Applications can be made for an original approval; or the amendment, replacement or renewal of an approval.

Clause 17 provides that the chief executive must consider an application and decide to grant the application, grant the application subject to conditions or refuse to grant the application. Clause 17 also prescribes actions the chief executive must undertake if the chief executive has decided to grant the application, refuse to grant the application, impose conditions (other than those sought by the applicant) on the approval of the application or endorse or cancel an amendment application.

Chief executive may require information or documents

Clause 18 provides that before deciding an application for a manufacturing or wholesaling approval, the chief executive may investigate the applicant and require the applicant, pursuant to an information requirement notice, to provide information as part of this process.

Clause 18 prescribes timeframes within which the chief executive must give the applicant the information requirement notice, and also within which the applicant is expected to comply with the notice. Further, clause 18 provides that, if required, the information required must be verified by a statutory declaration. An applicant is taken to have withdrawn an application if the applicant does not comply with the chief executive's information requirement notice.

Chief executive may extend period for decision for complex application

Clause 19 provides that the chief executive may extend the time for considering an application for a manufacturing or wholesaling approval if the chief executive considers that, because of the complexity of matters to be decided, extra time is needed to consider the application. The chief executive may extend the period for considering the application by the reasonable number of days the chief executive considers necessary, and must give the applicant notice of the day the extended period ends.

Failure to decide application

Clause 20 provides that the chief executive is taken to have refused to grant an application for a manufacturing or wholesaling approval if the chief executive fails to decide the application within the following periods after the chief executive receives the application:

- for an original application for an approval – within 90 days
- for a renewal application for an approval – within 30 days
- for another type of application for an approval – within 60 days.

If the chief executive has given the applicant an information requirement notice, a period mentioned above starts from the day the chief executive receives the information required under the notice.

Clause 20 also provides that if the chief executive has extended the period for deciding the application under clause 19 and does not decide the application within the extended period, the chief executive is taken to have refused to grant the application.

Further, if the chief executive is taken to have refused to grant application under this clause, the chief executive must give the applicant an information notice for the deemed refusal.

Division 3 Grant of approvals

Subdivision 1 Conditions, term and transfer

Standard conditions for manufacturing approvals

Clause 21 prescribes a number of standard conditions to which a manufacturing approval is subject.

Standard conditions for wholesaling approvals

Clause 22 prescribes a number of standard conditions to which a wholesaling approval is subject.

Additional or varied conditions for approvals

Clause 23 provides that if the chief executive reasonably believes it is necessary for an additional or varied condition to apply to an approval, the chief executive, when granting the approval, may impose additional conditions for the approval or vary a standard condition by stating the variation in the instrument for the approval.

Term of approvals

Clause 24 provides that an approval remains in force for the term decided by the chief executive and stated in the approval, unless sooner cancelled, suspended or surrendered. A term decided by the chief executive may not be more than two years.

Transfer of approvals prohibited

Clause 25 provides that an approval cannot be transferred.

Subdivision 2 Form of approvals

Form of manufacturing approval

Clause 26 prescribes the information that an instrument for a manufacturing approval must contain.

Form of wholesaling approval

Clause 27 prescribes the information that an instrument for a wholesaling approval must contain.

Division 4 Amendment, replacement and renewal of approvals

Subdivision 1 Preliminary

Making applications

Clause 28 provides that an application for the amendment, replacement or renewal of a manufacturing or wholesaling approval must be made to the chief executive and be in the approved form.

Process for deciding application

Clause 29 provides that subject to this division, an application for the amendment, replacement or renewal of a manufacturing or wholesaling approval must be decided under part 2, division 2, subdivision 4 (Process for deciding applications).

Subdivision 2 Amendment

Application by holder to amend approval

Clause 30 provides that the holder of an approval may apply to the chief executive to amend the approval (an *amendment application*) in relation to:

- the type or form of medicinal cannabis that may be manufactured or wholesaled under the approval
- the conditions applying to the approval, or
- another thing stated in the approval.

Minor amendment of approval by chief executive

Clause 31 provides that the chief executive may amend an approval on the chief executive's own initiative if the amendment is only for a formal or clerical reason, or another reason the chief executive reasonably believes will not adversely affect the interests of the approval holder.

Clause 31 also provides that if the chief executive decides to make an amendment, the chief executive must give the approval holder notice of the following as soon as practicable after the decision has been made:

- the amendment decided by the chief executive
- the reason for the amendment, and
- if the chief executive decides to endorse the instrument for the approval – that the holder must return the instrument to the chief executive to have it endorsed.

Subdivision 3 Replacement

Application for replacement of approval

Clause 32 provides that the holder of an approval may apply for the replacement of the approval (a *replacement application*) if the instrument for the approval has been damaged, destroyed, lost or stolen.

Criteria for deciding replacement application

Clause 33 provides that 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

Application for renewal of approval

Clause 34 provides that an approval holder may apply to the chief executive to renew the approval (a *renewal application*) within the period starting 60 days before the term of the approval ends. However, clause 34 also enables the chief executive to accept a renewal application made within 30 days after the term of the approval ends if satisfied it is reasonable to do so in the circumstances.

Approval taken to be in force while renewal application considered

Clause 35 applies if a renewal application for an approval is made before the approval expires. It provides that an approval is taken to continue in force from the day that, apart from this section, the approval would have expired, until the application is:

- decided under clause 17, or
- taken to have been withdrawn under clause 18.

This does not apply if the approval is earlier suspended or cancelled under division 8 of part 2.

Clause 35 further provides that if the application is refused, or taken to be refused under clause 20, the approval continues in force until the information notice for the approval is given to the applicant.

Division 5 Return and surrender of approvals

Return of instrument of approval

Clause 36 applies if the approval holder is required to return the original instrument for the approval to the chief executive, or the approval holder receives a replacement instrument for the approval and subsequently finds the original instrument.

Clause 36 provides that the approval holder must return the original instrument for the approval to the chief executive within one of the following periods, unless the holder has a reasonable excuse:

- if the holder has received a notice from the chief executive requiring the return of the instrument – 7 days after receiving the notice, or
- if the holder finds the original instrument – as soon as practicable after finding the instrument.

A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 6 Authority under approvals

Manufacturing approval does not grant authority to manufacture

Clause 37 provides that a manufacturing approval does not, of itself, grant the manufacturer authority to manufacture medicinal cannabis under the *Public Health (Medicinal Cannabis) Act 2016* (the Act). Section 92(2)(b) of the Act provides that a person may manufacture medicinal cannabis if the person is authorised to manufacture medicinal cannabis in accordance with an applicable law of the Commonwealth.

To obtain Commonwealth authorisation to manufacture medicinal cannabis, a person must apply to both the Office of Drug Control (ODC) for a licence to manufacture and the Therapeutic Goods Administration for a Good Manufacturing Practice licence. The person must then obtain a permit to manufacture from ODC. Before a manufacturing permit will be

granted, the person must provide evidence that they hold the necessary State or Territory licence or approval where one is required by the relevant State or Territory.

Authority under wholesaling approval

Clause 38 prescribes the activities a wholesaler is authorised to carry out under a wholesaling approval, and outlines the wholesaler's obligations in exercising the authority. It provides that a wholesaler may wholesale the type and form of medicinal cannabis stated in their approval to a single-patient prescriber, patient-class prescriber, pharmacist or someone in another State who may obtain medicinal cannabis under the law of the other State.

Division 7 Particular provisions for wholesaling approvals

Wholesaling code

Clause 39 provides that a wholesaler must, when exercising their authority under clause 38, comply with the code entitled the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8*. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

However, this provision 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.

Wholesaler to give invoice when wholesaling medicinal cannabis

Clause 40 provides that a wholesaler must, when wholesaling medicinal cannabis to a person, give the person an invoice that has a unique number, states the date of the wholesale and name and address of the person to whom the medicinal cannabis was sold, and describes the type and form, and quantity of volume, of the medicinal cannabis sold. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

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

Clause 41 provides that 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 (an *automatic approval*):

- for the type and form of medicinal cannabis the person may manufacture under the manufacturing approval, and
- for the same term as the manufacturing approval.

Further, clause 41 provides that, in relation to the manufacturing approval:

- if the chief executive renews the approval the chief executive must also renew the automatic renewal for the same term as the approval
- if the chief executive suspends the approval, the chief executive must also suspend the automatic approval for the same period
- if the chief executive cancels the approval the chief executive must also cancel the automatic approval

- if the chief executive varies the type or form of medicinal cannabis the person may manufacture under the approval, or amends the approval in another way, the chief executive must also amend the automatic approval in the same way, and
- if the person surrenders the approval the person is also taken to have surrendered the automatic approval.

Division 8 Administrative action

Definitions for division

Clause 42 provides the definitions for division 8 of part 2 of the regulation.

Grounds for action to be taken

Clause 43 prescribes that the chief executive may take administrative action in relation to an approval if:

- the approval holder has contravened the Act or a condition of the approval
- the chief executive believes the administrative action is necessary to prevent or minimise a diversion risk or a substance risk
- the approval holder is not, or is no longer, suitable to hold the approval
- the approval holder made a materially false or misleading representation or declaration to obtain the approval.

Show cause notice

Clause 44 applies if the chief executive reasonably believes a ground exists to take administrative action in relation to an approval. It provides that the chief executive must give the approval holder a notice under this section (a *show cause notice*).

Clause 44 prescribes the information that must be stated in the show cause notice, and provides that 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.

Representations about show cause notices

Clause 45 provides that an approval holder may make written representations to the chief executive about the show cause notice within the show cause period for the notice, and that the chief executive must consider all representations (the *accepted representations*) made under this provision.

Ending show cause process without further action

Clause 46 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. Clause 46 provides that the chief executive must not take any further action about the show cause notice, and must give notice to the approval holder that no further action is to be taken about the show cause notice.

Decision to take administrative action

Clause 47 applies if there are no accepted representations for the show cause notice, or if after considering the accepted representations from the approval holder for the show cause notice, the chief executive:

- still reasonably believes a ground exists to take administrative action in relation to the approval, and
- reasonably believes the administrative action is warranted.

Clause 47 prescribes the administrative action that the chief executive may take in relation to the approval, and provides that as soon as practicable after making the decision the chief executive must give an information notice about the decision to the approval holder. The decision takes effect on the day the information notice is given to the holder or, if a later day is stated in the information notice, the later day.

Immediate administrative action

Clause 48 provides that the chief executive may decide to immediately take action in relation to an approval if the chief executive reasonably believes:

- a ground exists to take the administrative action in relation to the approval, and
- 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.

The administrative action takes effect when both a show cause notice for the administrative action and an information notice for the chief executive's decision to take the action are given to the approval holder. The administrative action continues in effect until the earliest of the following:

- the chief executive decides to stop the administrative action
- the show cause notice is finally dealt with, or
- 60 days after the notices were given to the holder.

Division 9 Offences

Offence for false or misleading statements or documents

Clause 49 provides that a person must not state anything, or give a document containing information, the person knows is false or misleading in relation to:

- an application for an approval,
- an application for the amendment, replacement or renewal of an approval, or
- a response to a request for information under clause 18 from the chief executive.

A maximum penalty of 20 penalty units applies for non-compliance with this provision

Offence for failure to comply with approval conditions

Clause 50 provides that a person must comply with the conditions of an approval that apply to the person, unless the person has a reasonable excuse. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Part 3 Other dealings with medicinal cannabis

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

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

Clause 51 prescribes a range of standard conditions for medicinal cannabis approvals, for the purpose of section 34(1) of the Act. Clause 51 also defines a number of terms for the provision.

One of the standard conditions requires approval holders to obtain a writing driving acknowledgement from their patient before exercising their authority, if the patient is a driving restricted patient. *Driving restricted patient* is defined for the section to mean a patient who is at least 16 years old, has capacity to consent to treatment with medicinal cannabis and will be treated with medicinal cannabis containing delta-9-tetrahydrocannabinol (THC). *Written driving acknowledgement* is defined in schedule 2 as 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 they have THC in their blood or saliva. This condition will ensure that any patient who may hold a driver licence is made aware of their responsibilities under relevant transport legislation not to drive while THC is present in their system.

In addition, clause 51 requires that medicinal cannabis products containing THC should have a warning label attached stating that the patient is not permitted to drive a motor vehicle or operate machinery while taking the medication.

The approval holder is also required to keep the written driving acknowledgement, in accordance with the record-keeping requirements under part 6.

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

Clause 52 prescribes a range of standard conditions for dispensing approvals, for the purpose of section 34(1) of the Act. Clause 52 also defines a number of terms for the provision.

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

Clause 53 prescribes the standard conditions for clinical approval trials, for the purpose of section 34(1) of the Act.

Division 2 Patient-class prescribers

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

Clause 54 prescribes the classes of specialist medical practitioners who may prescribe medicinal cannabis for section 52(1)(a) of the Act. Subsection (2) provides that a specialist medical practitioner who is not breaching a condition under clause 57(2)(a) or (b) and has not breached a condition under clause 57(2)(a) or (b) is compliant. Only compliant specialist medical practitioners are prescribed for the purposes of clause 54.

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

Clause 55 prescribes the class of patients for section 52(2)(a) of the Act to whom a member of the class of specialist medical practitioners may prescribe medicinal cannabis. The clause also provides a definition for *terminally ill person*.

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

Clause 56 prescribes the type of medicinal cannabis for section 52(2)(b) of the Act with which a member of the class of specialist medical practitioners may treat a member of the class of patients. Clause 56 prescribes medicinal cannabis containing either THC or cannabidiol (CBD), or a combination of both.

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

Clause 57 prescribes conditions for section 52(1)(b) of the Act applying to the way in which the class of specialist medical practitioners may exercise the authority given to them under chapter 4 of the Act. Clause 57 also defines a number of terms for the provision.

Consistent with the standard condition for medicinal cannabis approval holders, patient-class prescribers are required to obtain and keep a written driving acknowledgement from their patient, if the patient is a driving restricted patient.

Division 3 Restricted access patients

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

Clause 58 provides for prescribed persons pursuant to the definition in section 61(7) of the Act of *prescribed person*, for the purpose of treating a restricted access patient in the care of a state school, non-state school, QEC approved service, or approved education and care service.

Clause 58 also defines a number of terms for the provision. *Approved provider*, in relation to an approved education and care service, is defined by reference to the Education and Care Services National Law (Queensland), section 5. In relation to a QEC approved service, *approved provider* is defined by reference to the *Education and Care Services Act 2013*, schedule 1.

Division 4 Authorised ways and eligible persons

Subdivision 1 Preliminary

Definitions for division

Clause 59 provides the definitions for division 4 of part 3 of the regulation.

Eligible persons and authorised ways—Act, s 68

Clause 60 provides that pharmacy technicians, and state analysts and trainee state analysts, are prescribed as eligible persons for section 68(3) of the Act, in addition to the categories of eligible persons provided in section 68(3)(a) and (b) of the Act.

Clause 60 also provides that for section 68(1) 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

Dosage conditions do not apply to authorised hospital staff members

Clause 61 provides that a dosage condition for a relevant patient does not apply to a hospital staff member. The term *dosage condition* is defined as a condition relating to the dosage of medicinal cannabis that may be prescribed for or used by the patient:

- stated in the medicinal cannabis approval or clinical trial approval, or
- imposed under section 34(2), 35(2) or 52(1)(b) of the Act.

Authority ends when relevant patient leaves hospital

Clause 62 provides that 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.

Use of patient-supplied medicinal cannabis

Clause 63 applies to patient-supplied medicinal cannabis of a relevant patient and provides that nothing in division 4 authorises an authorised hospital staff member to deal with the patient-supplied medicinal cannabis in a way that causes it to be used to treat a patient other than the relevant patient.

Clause 63 also provides that 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 the patient, or a carer or another person authorised to obtain and possess medicinal cannabis for the patient.

Hospital doctors

Clause 64 applies if a doctor is employed or contracted to practise medicine at a hospital, and a relevant patient is being treated at the hospital. Clause 64 provides that to the extent necessary to practise medicine at the hospital, the doctor is authorised to:

- obtain patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis and possess the medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital
- 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:
  - issue the medicinal cannabis to an authorised hospital staff member at the hospital who is treating the patient, or
  - administer the medicinal cannabis to the patient at the hospital,
- 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.

Enrolled nurses

Clause 65 applies if an enrolled nurse is employed or contracted to practise nursing at a hospital, and a relevant patient is being treated at the hospital. Clause 65 provides that to the extent necessary to practise nursing at the hospital, the enrolled nurse is authorised to:

- possess patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital,
- administer the medicinal cannabis to the patient at the hospital:
  - in accordance with a written instruction of a doctor employed or contracted to practise medicine at the hospital, and
  - 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.

However, the authorisations do 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.

Registered nurses

Clause 66 applies if a registered nurse is employed or contracted to practise nursing at a hospital, and a relevant patient is being treated at the hospital. Clause 66 provides that to the extent necessary to practise nursing at the hospital, the registered nurse is authorised to:

- possess patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis when at the hospital for the purpose of treating the patient at the hospital,
- 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.

Pharmacists

Clause 67 provides that a pharmacist practising at a hospital 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 it to an authorised hospital staff member at a hospital for the treatment of a relevant patient at the hospital
- obtain medicinal cannabis that is not patient-supplied medicinal cannabis (*hospital-dispensed 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 it for the purpose of treating a relevant patient at the hospital to the patient, or a carer or another person authorised to obtain and possess medicinal cannabis for the patient
- dispense hospital-dispensed medicinal cannabis to the patient, or a carer or another person authorised to obtain and possess medicinal cannabis for the patient, for the purpose of treating the patient at the hospital,
- issue patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis to an authorised hospital staff member at the hospital in accordance with the oral or written

instruction of a doctor employed or contracted to practise medicine at the hospital and for the purpose of treating a relevant patient at the hospital.

Clause 67 further provides that 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 in relation to a number of the above actions. This will ensure that in hospitals where there is no pharmacist present, the medicinal cannabis is able to be dispensed to the patient or their carer.

Pharmacy technicians

Clause 68 prescribes the authorised ways for pharmacy technicians to deal with medicinal cannabis under the personal supervision of a pharmacist present at the hospital. Clause 68 provides that to the extent necessary to perform their duties at a hospital, the pharmacy technician is authorised to:

- possess patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis mentioned in clause 67(2) and (3) at the hospital,
- issue patient-supplied medicinal cannabis or hospital-dispensed medicinal cannabis to an authorised hospital staff member at the hospital in accordance with the oral or written instruction of a doctor employed or contracted to practise medicine at the hospital and for the purpose of treating a relevant patient at the hospital.

Subdivision 3 State analysts and trainee State analysts

Manufacture of medicinal cannabis

Clause 69 provides that to the extent necessary to perform a State analyst's official duties, a State analyst is authorised to manufacture medicinal cannabis. Clause 69 also provides that a trainee State analyst under the personal supervision of a State analyst is authorised to manufacture medicinal cannabis.

Division 5 Offences

Misuse of written instruction for medicinal cannabis

Clause 70 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Clause 70 also provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Unsafe disposal or use of medicinal cannabis

Clause 71 provides that a person must not destroy, or otherwise dispose of or use, medicinal cannabis in a way that:

- endangers the life or safety or a person or domestic animal, or
- exposes food, drink, a condiment, a drug or a poison to the risk of contamination by the medicinal cannabis, or
- allows access to medicinal cannabis to someone not authorised to possess it.

A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 6 Medicinal cannabis management plans

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

Clause 72 provides that a medicinal cannabis management plan made by a person required to comply with the security standard under clause 124 must state how the person will store the medicinal cannabis in a way that complies with the security standard.

Part 4 Lawful directions

Division 1 Lawful directions generally

Preventing fraudulent lawful directions

Clause 73 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 2 Prescriptions

Subdivision 1 Prescriptions generally

Prescriptions for medicinal cannabis

Clause 74 provides that a prescriber, when prescribing medicinal cannabis, must comply with division 2. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Form of prescriptions

Clause 75 provides that a prescription must be signed by the prescriber, be legible, use terms or symbols used in the ordinary practice of the prescriber's profession, and if the prescription is amended or corrected – use terms or symbols to show the amendment or correction is made by the prescriber.

Content of prescriptions

Clause 76 prescribes the information that must be included in a prescription and provides that the prescription must not prescribe more than one item, with an exception that the prescription may prescribe more than one item if each item is for medicinal cannabis (including different types or forms of medicinal cannabis). Clause 76 further provides that

prescriptions for medicinal cannabis must not include a repeat. Clause 76 also contains definitions for the provision.

Subdivision 2 Paper prescriptions

Paper prescriptions generated by computer

Clause 77 provides that a computer-generated paper prescription must be generated in a way that complies with schedule 1 of this regulation.

Electronic communication of paper prescriptions

Clause 78 provides that a prescriber may provide a paper prescription to a dispenser using electronic communication (such as facsimile or email). If doing so, the prescriber must:

- telephone the dispenser and confirm the details of the paper prescription within 24 hours of sending the prescription using electronic communication, and
- provide the paper prescription to the dispenser within 7 days of sending the prescription using electronic communication.

Subdivision 3 Electronic prescriptions

Electronic prescriptions

Clause 79 prescribes a range of conditions concerning the use of electronic prescriptions.

Part 5 Dispensing medicinal cannabis

Division 1 Packaging and labelling

Packaging

Clause 80 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision. The person is taken to have complied with this provision if the medicinal cannabis is packaged in a way that complies with another law of Queensland or the Commonwealth stating requirements for the packaging of medicinal cannabis.

Labelling generally

Clause 81 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision. A person is taken to have complied with this provision if the label complies with another law of the State or Commonwealth stating requirements for the labelling of medicinal cannabis.

Labelling by pharmacist

Clause 82 applies to a pharmacist who dispenses medicinal cannabis. It provides that the pharmacist must attach a label to the manufacturer's package of the medicinal cannabis, ensuring the label does not obscure the instructions for the use of the medicinal cannabis; and also prescribes the information that must be stated on the label. A maximum penalty of 20 penalty units applies for non-compliance with the requirements of this provision.

Labelling by single-patient prescribers and patient-class prescribers

Clause 83 applies to a single-patient prescriber or a patient class prescriber (the doctor) who issues or supplies medicinal cannabis. It provides that the doctor must attach a label to the manufacturer's package of the medicinal cannabis, ensuring the label does not obscure the instructions for the use of the medicinal cannabis; and also prescribes the information that must be stated on the label. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Warnings to be printed on labels

Clause 84 provides that a person required to attach a label to a manufacturer's package under clause 82 or 83 must also ensure the label has the following warnings printed on it:

- 'Keep out of reach of children'
- 'This medication may cause drowsiness and may increase the effects of alcohol', and
- for medicinal cannabis containing THC (whether or not the medicinal cannabis also contains cannabidiol) – 'Do not drive a motor vehicle or operate machinery while taking this medication'.

A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Clause 84 provides that a warning label does not need to be printed on the label if the warning appears on the manufacturer's package and is clearly visible after the label is attached to the manufacturer's package.

Chief executive may approve alternative packaging or labelling

Clause 85 provides that the chief executive may approve a way (an *alternative way*) of packaging or labelling medicinal cannabis, either on application or on the chief executive's own initiative. The chief executive must only approve an alternative way if reasonably satisfied the alternative way is as safe as the packaging or labelling requirements for medicinal cannabis under the current Poisons Standard.

Clause 85 also provides that the approval may be subject to conditions and apply to a stated person packaging or labelling medicinal cannabis in a particular way, or a stated form or type of medicinal cannabis. If the approval applies to a stated type or form of medicinal cannabis, the approval must be published on the department's website.

In a proceeding against a person for a packaging or labelling offence under clauses 80 to 84, it is a defence for the person to show that:

- for an offence against clause 80 – the way in which the person packaged the medicinal cannabis was in accordance with an approval under this section, or
- for an offence against clauses 81 to 84 – the way in which the person labelled the medicinal cannabis was in accordance with an approval under this section.

Restriction on using contaminated packages

Clause 86 provides that 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. A maximum penalty of 20 penalty points applies for non-compliance with this provision.

Restriction on selling in second-hand packages

Clause 87 applies to a person packaging medicinal cannabis for sale. It provides that the person must not use a package the person has previously used or knows has been previously used. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 2 Dispensing

When medicinal cannabis must be not dispensed

Clause 88 applies to a dispenser if they are asked to dispense medicinal cannabis on a prescription, and provides that the dispenser must not dispense the medicinal cannabis if it appears to have been prescribed more than three months before the date the prescription is presented to the dispenser. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Dealing with prescriptions

Clause 89 applies to a dispenser who dispenses medicinal cannabis on a prescription. It provides that a dispenser must, when dispensing the medicinal cannabis, annotate the prescription (the *annotated prescription*) with the following information:

- a statement that the prescription has been dispensed,
- the date,
- the name or initials of the dispenser, and
- the name and address of the dispenser's dispensary.

A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Clause 89 also provides that, within 72 hours after dispensing the medicinal cannabis the dispenser must send the chief executive:

- for a paper prescription – a copy of the annotated prescription in paper form, or in an approved electronic form by electronic means, or
- for an electronic prescription – the annotated prescription by electronic means.

A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Clause 89 further provides that the dispenser must keep a paper prescription in paper form. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Issuing, selling or supplying medicinal cannabis after expiry date

Clause 90 provides that a person must not issue, sell or supply medicinal cannabis after the expiry date for the medicinal cannabis stated on the manufacturer's package or a label attached to the manufacturer's package. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 3 Advertising medicinal cannabis

Advertising medicinal cannabis

Clause 91 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision. However, this provision does not apply to:

- an advertisement in a professional or trade journal, or
- a price list, advertisement or promotional material intended for circulation only to the wholesale drug trade or medicinal or pharmaceutical professions.

Clause 91 includes a definition of *advertise*.

Part 6 Record-keeping

Division 1 Record-keeping generally

Records may be made and kept electronically

Clause 92 provides that a person required to make or keep a record under the Act or this regulation may make or keep the record electronically, unless expressly stated otherwise in the relevant provision.

Recording information on paper

Clause 93 applies if a person writes information on a paper document in order to comply with a requirement under a provision of the Act or this regulation. Clause 93 provides that the information must be written legibly in ink and durably marked on the paper. A maximum penalty of 20 penalty units applies for non-compliance with this provision. The requirement to write legibly does not apply to the person's signature.

Keeping information

Clause 94 sets out the requirements applicable to a person responsible for controlling the recording and keeping of information under a provision of the Act or this regulation. The person is required to ensure the information is readily retrievable, cannot be altered, obliterated, deleted or removed without detection and is kept for a period of two years after the date the information is recorded. A maximum penalty of 20 penalty units applies for non-compliance with the provision.

Record to be made on day of transaction

Clause 95 provides that 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. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Stocktake

Clause 96 provides that a person who, under the Act or this regulation, is required to make or keep a record of the amount of medicinal cannabis the person possesses or otherwise keeps at a place, must perform a stocktake at particular intervals. Clause 96 also details the actions that must be carried out by a person when undertaking the stocktake. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Discrepancy to be immediately reported to chief executive

Clause 97 applies to a person who is required under the Act or this regulation to keep or update a record book, keep or update records or ensure records are kept about transactions involving medicinal cannabis, and who:

- finds a discrepancy between the quantity or volume of a type or form of medicinal cannabis to which the record relates, and the quantity or volume of the type or form medicinal cannabis stated in the record, or
- knows, or reasonably suspects, the medicinal cannabis has been lost, misappropriated or stolen.

Clause 97 provides that the person must immediately give the chief executive a written notice about the discrepancy, loss, misappropriation or theft. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Records not to be changed but may be corrected

Clause 98 provides that a person must not cancel, change or obliterate an entry made in a book or other record kept under the Act or this regulation. A maximum penalty of 20 penalty units applies for non-compliance with this provision. However, the person who made the entry may correct the entry by a signed and dated marginal note or footnote giving the correct details.

False, misleading or incomplete entries

Clause 99 provides that a person must not make an entry in a book or record required to be kept under the Act or this regulation if person knows the entry is false, misleading or incomplete. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 2 Record-keeping by particular doctors

Particular doctors to record transactions involving medicinal cannabis

Clause 100 applies to a doctor other than a doctor employed or contracted to practise medicine at a hospital or a nursing homes, as division 5 sets out separate record-keeping requirements relating to hospitals and nursing homes. Clause 100 provides that a doctor must

record transactions involving medicinal cannabis in the doctor's record book, and outlines requirements for the way transactions must be recorded. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 3 Record-keeping by pharmacists

Definition for division

Clause 101 provides definitions for division 3 of part 6 of the regulation.

Pharmacists to record transactions involving medicinal cannabis in controlled drugs record

Clause 102 provides that 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 provision and clause 103. A maximum penalty of 20 penalty units applies for non-compliance with this provision. Clause 102 outlines requirements for the way the transactions must be recorded.

Entries to be made in controlled drugs record

Clause 103 provides that if there is more than one transaction on a day, the pharmacist must enter the details of each transaction in the controlled drugs records in the order in which the transactions happen. Clause 103 also outlines the details the pharmacist must include for each entry, and the ways in which a pharmacist must endorse transactions made in a controlled drugs record kept in a book or a controlled drugs record kept in another form.

Pharmacist to keep documents

Clause 104 provides that a pharmacist must keep all documents relating to medicinal cannabis dispensed by the pharmacist. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Division 4 Record-keeping by wholesalers

Records of transactions to be kept by wholesalers

Clause 105 provides that a wholesaler must keep a record of transactions that are the wholesale of medicinal cannabis (a *wholesaler's register*), and outlines requirements for the way transactions must be recorded. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Subsection (7) provides that if the wholesaler is required to keep a controlled drugs register for controlled drugs sold by the wholesaler under section 50 of the *Health (Drugs and Poisons) Regulation 1996*, the requirement under subsection (1) must be complied with by ensuring transactions involving the wholesale of medicinal cannabis are recorded in the controlled drugs register. This avoids duplication for wholesalers in complying with their requirements under both pieces of legislation.

Division 5 Record-keeping by hospitals and nursing homes

Subdivision 1 Preliminary

Definitions for division

Clause 106 provides the definitions for division 5 of part 6 of the regulation.

Subdivision 2 Hospitals and nursing homes with multiple storage points

Application of subdivision

Clause 107 provides that this subdivision applies to a hospital or nursing home that has more than one storage point for medicinal cannabis.

Main issue book

Clause 108 provides for the requirement for the central storer to keep a record of particular transactions involving medicinal cannabis in the main issue book. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Subsection (3) provides that if a person is required to keep a main issue book for controlled drugs under section 99 of the *Health (Drugs and Poisons) Regulation 1996*, the requirement under subsection (1) must be complied with by ensuring transactions involving medicinal cannabis are recorded in the main issue book for controlled drugs. This avoids duplication for hospitals and nursing homes in complying with their requirements under both pieces of legislation.

Details to be recorded in main issue book

Clause 109 provides for the requirement for the central storer to record particular information in the main issue book for transactions mentioned in clause 108(1), and to sign the entry. If the medicinal cannabis is issued to a unit storer for a unit, there is a requirement for the unit storer to sign the entry. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Ward book

Clause 110 provides for the requirement for a unit storer for a unit to keep a record of particular transactions involving medicinal cannabis in the ward book. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Subsection (3) provides that if a person is required to keep a ward drugs book for controlled drugs at a unit under section 101 of the *Health (Drugs and Poisons) Regulation 1996*, the requirement under subsection (1) must be complied with by ensuring transactions involving medicinal cannabis are recorded in the ward drugs book. This avoids duplication for hospitals and nursing homes in complying with their requirements under both pieces of legislation.

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

Clause 111 provides for the requirement for a unit storer for a unit to record particular information in the ward book for transactions mentioned in clause 110(1)(a). A maximum penalty of 20 penalty units applies for non-compliance with this provision.

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

Clause 112 provides for the requirement for a unit storer for a unit to record particular information in the ward book for transactions mentioned in clause 110(1)(b). A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Transfer vouchers may be used for medicinal cannabis in certain cases

Clause 113 applies where it is not practicable for a unit storer to sign the main issue book or for the central storer to sign the ward book because of the size of a hospital or nursing home, or for another reason.

Clause 113 provides that the central storer and unit storer may record particular transactions involving medicinal cannabis on a transfer voucher, which is a document stating the things that must be recorded in a main issue book and ward book.

Subsection (3) requires relevant persons to sign the transfer voucher. A maximum penalty of 20 penalty units applies for non-compliance with subsection (3).

Main issue book and ward book as 1 book

Clause 114 provides that clauses 110 to 112 do not apply to unit storers at a hospital or nursing home if the central storer keeps one book that contains the information that must be recorded in the main issue book and each ward book, and entries in the book are signed by the relevant person.

Subsection (2) provides that if a person keeps a single book for controlled drugs under section 105 of the *Health (Drugs and Poisons) Regulation 1996*, the single book kept under subsection (1) must be a single book for controlled drugs under the *Health (Drugs and Poisons) Regulation 1996*. This avoids duplication for hospitals and nursing homes in complying with their requirements under both pieces of legislation.

Subdivision 3 Hospitals and nursing homes with 1 storage point

Application of subdivision

Clause 115 provides that this subdivision applies to a hospital or nursing home that has one storage point for medicinal cannabis.

Single storage book

Clause 116 provides for the requirement for a single storer to keep a record of particular transactions involving medicinal cannabis in the single storage book. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Subsection (3) provides that if a person is required to keep a single storage book for controlled drugs under section 106 of the *Health (Drugs and Poisons) Regulation 1996*, the requirement under subsection (1) must be complied with by ensuring transactions involving medicinal cannabis are recorded in the single storage book for controlled drugs. This avoids duplication for hospitals and nursing homes in complying with their requirements under both pieces of legislation.

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

Clause 117 provides for the requirement for a single storer to record particular information in the single storage book for transactions mentioned in clause 116(1)(a). A maximum penalty of 20 penalty units applies for non-compliance with this provision.

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

Clause 118 provides for the requirement for a single storer to record particular information in the single storage book for transactions mentioned in clause 116(1)(b). A maximum penalty of 20 penalty units applies for non-compliance with this provision.

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

Responsibility for checking accuracy of records at hospitals and nursing homes

Clause 119 provides for the requirements for a responsible person for a hospital or nursing home, or a person otherwise in charge of a hospital or nursing home, to keep and check the accuracy of records. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Part 7 Transportation and delivery of medicinal cannabis

Definitions for part

Clause 120 provides the definitions for part 7 of the regulation.

Sending and delivering medicinal cannabis

Clause 121 provides for an offence where a seller delivers or sends medicinal cannabis to a buyer contrary to clauses 122 or 123. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Delivery of medicinal cannabis

Clause 122 provides for the requirements for a seller, or an adult employee of the seller, delivering medicinal cannabis to a buyer, or an adult employee of the buyer.

Sending medicinal cannabis by carrier

Clause 123 provides for the requirements for a seller sending medicinal cannabis to a buyer by carrier.

Part 8 Storage of medicinal cannabis

Relevant person must comply with standard

Clause 124 provides for the relevant persons who must comply with the storage requirements set out in the Standard for Security of Medicinal Cannabis Stock, which can be obtained on the Queensland Health website. Single-patient prescribers, patient-class prescribers, pharmacists, manufacturers, wholesalers and responsible persons for an institution that is a hospital or nursing home are relevant persons for clause 124. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Part 9 Notification and reporting

Definition for part

Clause 125 provides a definition for part 9 of the regulation.

Single-patient prescribers

Clause 126 provides that a single-patient prescriber must provide treatment reports to the chief executive about each patient they are treating with medicinal cannabis, at the frequency stated in their medicinal cannabis approval. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Patient-class prescribers

Clause 127 provides for a patient-class prescriber's notification requirements. A patient class-prescriber is required to give notice to the chief executive in the approved form within seven days of giving an initial lawful direction in relation to a particular eligible patient's treatment with medicinal cannabis. A patient-class prescriber must also provide treatment reports to the chief executive about each eligible patient they are treating with medicinal cannabis, at the frequency stated in the Queensland Clinical Guidance for Medicinal Cannabis, which is available on the Queensland Health website. A maximum penalty of 20 penalty units applies for non-compliance with this provision.

Part 10 Transitional provisions

Definitions for part

Clause 128 provides definitions for part 10 of the Regulation.

Existing licence to manufacture medicinal cannabis

Clause 129 provides that if a person was the holder of a controlled drug manufacturer licence under the *Health (Drugs and Poisons) Regulation 1996* immediately before commencement of the Regulation, they are taken to be the holder of a manufacturing approval under the Regulation for the type and form of medicinal cannabis the person is authorised to manufacture under the controlled drug manufacturer licence.

Existing application for controlled drug manufacturer licence

Clause 130 applies if a person has applied for a controlled drug manufacturer licence and immediately before commencement of the Regulation, the application has not been decided. Clause 130 provides that the person is taken to have applied (a deemed application) for a manufacturing approval under the Regulation for the type and form of medicinal cannabis stated in the application for the controlled drug manufacturer licence. The chief executive is required to decide the deemed application under the Regulation.

Existing licence to wholesale medicinal cannabis

Clause 131 provides that if a person was the holder of a controlled drug wholesaler licence under the *Health (Drugs and Poisons) Regulation 1996* immediately before commencement of the Regulation, they are 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.

Existing application for controlled drug wholesaler licence

Clause 132 applies if a person has applied for a controlled drug wholesaler licence and immediately before commencement of the Regulation, the application has not been decided. Clause 132 provides that the person is taken to have applied for a wholesaling approval under the Regulation for the type and form of medicinal cannabis stated in the application for the controlled drug wholesaler licence. The chief executive is required to decide the deemed application under the Regulation.

Schedule 1 Computer-generated paper prescriptions

Prescription form must be preprinted

Clause 1 provides that a computer-generated paper prescription must be generated on a preprinted form with particular information preprinted on the form, consistent with the requirements in appendix 4, section 1 of the *Health (Drugs and Poisons) Regulation 1996* in relation to computer-generated paper prescriptions for a controlled or restricted drug.

Only prescriber may generate prescription

Clause 2 provides that the computer program used to generate a computer-generated paper prescription must allow only a prescriber to generate the prescription, consistent with the requirements in appendix 4, section 2 of the *Health (Drugs and Poisons) Regulation 1996*.

Requirements on generation of prescription

Clause 3 sets out the requirements for when a computer-generated paper prescription is generated, consistent with the requirements in appendix 4, section 4 of the *Health (Drugs and Poisons) Regulation 1996*.

System messages

Clause 4 provides that the computer program used to generate a computer-generated paper prescription must generate a message for the prescriber relating to the particulars mentioned

in clause 76(1)(h) to (k), consistent with the requirements in appendix 4, section 5 of the *Health (Drugs and Poisons) Regulation 1996*.

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

Clause 5 provides that for a computer-generated paper prescription, the particulars set out in clause 76(1)(e) and (f) may be generated by the computer, consistent with the requirements in appendix 4, section 6 of the *Health (Drugs and Poisons) Regulation 1996*.

Schedule 2 Dictionary

Schedule 2 inserts definitions for key terms used in the regulation.