Public Health (Medicinal Cannabis) Bill 2016

Explanatory Notes

Short title

The short title of the Bill is the Public Health (Medicinal Cannabis) Bill 2016 (the Bill).

Policy objectives and the reasons for them

There is a growing body of evidence about the therapeutic potential of medicinal cannabis, in particular that cannabinoids (being the substances contained within cannabis that produce pharmacological effects) may be effective for the treatment of neuropathic pain, muscle spasticity for patients with multiple sclerosis, reducing seizures in children with treatment resistant epilepsy, wasting due to HIV/AIDS and in controlling nausea for cancer patients. Treatment with medicinal cannabis for these conditions and symptoms may have a positive impact on a patient's quality of life, particularly where traditional treatments have failed and the potential benefits outweigh the risks of any unwanted side effects.

Under the existing regulatory framework comprising the *Commonwealth Therapeutic Goods Act 1989* (Cwth) and *Narcotic Drugs Act 1967* (Cwth), and the Queensland *Drugs Misuse Act 1986* and *Health (Drugs and Poisons) Regulation 1996*, cannabis is a prohibited substance.

Cannabis remains a prohibited substance as it is a dependence-forming drug and there is evidence that over time it causes harm, particularly in young people. In Queensland, the controls in the *Drugs Misuse Act 1986* operate to prevent harm to the community from the use of illicit drugs, and make it an offence to produce, possess and supply cannabis without authorisation, justification or lawful excuse.

However, the policy position of the Queensland Government is to allow greater use of medicinal cannabis products under certain circumstances and for specific patients. To facilitate this, the government amended the *Health (Drugs and Poisons) Regulation 1996* in late 2015 to allow the chief executive of Queensland Health to approve the use of certain medicinal cannabis products for a clinical trial or where the Commonwealth Therapeutic Goods Administration (TGA) has approved an individual accessing those products.

In line with this policy position, a more comprehensive regulatory framework is required to effectively regulate the use of medicinal cannabis products.

The objective of the *Public Health (Medicinal Cannabis) Bill 2016* is to create a new regulatory framework under which medicinal cannabis products may be prescribed and dispensed to patients in Queensland while also preventing their unauthorised use.

Achievement of policy objectives

The Bill will achieve the policy objectives by establishing a regulatory framework to facilitate treatment with medicinal cannabis, while preventing unauthorised use.

The regulatory framework in the Bill 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 having 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.

To become a patient-class prescriber, a doctor must be within the class of specialists listed in the regulation. The regulation will also impose standard and additional conditions on this as-of-right authority to prescribe medicinal cannabis, such as a requirement to notify the chief executive when the specialist prescribes, supplies or administers medicinal cannabis, or a requirement to comply with a stated code, guideline, protocol or standard.

In contrast, a medicinal cannabis approval, dispensing approval or clinical trial approval all involve case-by-case application, consideration, approval and review processes. For a medicinal cannabis approval, the processes are detailed below:

1. The medical practitioner treating a **patient** must discuss treatment with **medicinal cannabis** with the patient, and obtain written consent to the treatment. The **medical practitioner** may be a general medical practitioner or specialist medical practitioner.
2. The medical practitioner must apply to the chief executive of Queensland Health for a **medicinal cannabis approval**. This approval authorises the medical practitioner to treat their patient with medicinal cannabis. The application must include:
    a. a copy of the patient's written consent
    b. a copy of any specialist medical opinion previously obtained in relation to the patient's treatment with medicinal cannabis.
3. When deciding the application, the chief executive may have regard to a range of factors, including:
    a. the suitability of the medical practitioner to be granted a medicinal cannabis approval
    b. the suitability of the patient to be treated with medicinal cannabis
    c. the patient's medical condition
    d. the form and dosage of the medicinal cannabis proposed by the medical practitioner to treat the patient
    e. whether treatment with medicinal cannabis can be integrated into the patient's existing medical treatment
    f. any alternative treatments suitable for the patient's medical condition.

4. When deciding the application, the chief executive must be satisfied the TGA has approved access to the medicinal cannabis product, or is capable of approving access. This is because medicinal cannabis products generally cannot lawfully be supplied without both TGA and Queensland Government approval.
5. Before deciding the application, the chief executive may do the following:
    a. require the medical practitioner to provide additional information or documents
    b. require the medical practitioner to provide an opinion from a specialist medical practitioner, or from another specialist medical practitioner if an opinion has already been provided
    c. refer the application to the **expert advisory panel**, being the panel of experts established to provide advice and make recommendations to the chief executive.
6. The timeframes within which the chief executive must decide an application are:
    a. within 90 days after receiving the application
    b. if the chief executive has requested the applicant provide further information, within 90 days after the further information is received
    c. if the application is complex, within a reasonable time after the standard period, as decided by the chief executive.
7. If granted, the medicinal cannabis approval must note the following:
    a. details of the medical practitioner and the patient
    b. the form, dosage and dispensing intervals of the medicinal cannabis product
    c. details of the pharmacy from where the medicinal cannabis will be dispensed (called the **dispensing pharmacy**)
    d. the term of the approval (which must not exceed one year).
8. The medicinal cannabis approval is subject to any standard conditions prescribed by regulation. The chief executive may also impose additional conditions on specific approvals.
9. A medical practitioner granted a medicinal cannabis approval is called a **single-patient prescriber**, and is authorised to prescribe medicinal cannabis to treat a particular patient in their care, but only in accordance with the terms and conditions of the medicinal cannabis approval.
10. If the medicinal cannabis approval is not granted, the medical practitioner may apply for an internal review by Queensland Health of the decision. If the original decision is affirmed by the internal review, the medical practitioner may apply to Queensland Civil and Administrative Tribunal for a review of the original decision.

To support both the patient-class prescriber and single-patient prescriber frameworks, the chief executive will grant **dispensing approvals** to specific pharmacists (called **approved pharmacists**) to dispense medicinal cannabis. To lawfully dispense medicinal cannabis prescribed for a patient, an approved pharmacist must work in the dispensing pharmacy noted on the medicinal cannabis approval. A **secondary dispenser** noted on the dispensing approval may also lawfully dispense the medicinal cannabis at the dispensing pharmacy.

The patient's carer is authorised to obtain the medicinal cannabis prescribed for the patient from the dispensing pharmacy, possess the medicinal cannabis, and supply or administer the medicinal cannabis to the patient.

Sometimes, the patient's medical condition may prevent them from self-administering medicinal cannabis or the patient may be unable to possess or self-administer their medicinal cannabis because they are in an institution such as a hospital, school, nursing home or prison. In these circumstances, the patient is called a **restricted access patient** and a person with regular access to the patient (called a **facilitator**) is authorised to possess, supply or administer medicinal cannabis to the patient. If the patient is in an institution, the person in charge of the institution, person in charge of providing health care for the institution or a person in charge of dispensing drugs for the institution (called a **responsible person**) must develop a **medicinal cannabis management plan** to manage the risks associated with possessing, supplying or administering medicinal cannabis.

In addition to authorising treatment of a specific patient under a medicinal cannabis approval, the chief executive may also grant a **clinical trial approval** to facilitate the treatment of patients enrolled in a recognised medicinal cannabis clinical research trial.

An expert panel will be established, to advise and assist the chief executive, including determining the specific conditions and medicinal cannabis products for which a medicinal cannabis approval may be considered, and identifying suitable alternative treatments and other specific medical concerns relevant to the chief executive's assessment of an application.

Any cannabis use outside of the proposed regulatory framework will remain illegal, and the framework will ensure appropriate powers are available to prevent misuse and the risk of the medical cannabis being dispensed, supplied or issued to a person not authorised under the legislation.

This includes the appointment of authorised persons to investigate, monitor and enforce compliance with the Bill. The framework also provides the chief executive with the powers to suspend, cancel, vary or impose conditions on a medicinal cannabis approval.

The following are key terms used throughout the Bill, including those in bold above:

- *'medicinal cannabis'* – a cannabis product used for human therapeutic purposes, but not a product already registered on the Australian Register of Therapeutic Goods (ARTG)
- *'approval'* - a medicinal cannabis approval, dispensing approval or a clinical trial approval
- *'medicinal cannabis approval'* – an approval granted to a medical practitioner to treat a patient with medicinal cannabis
- *'single-patient prescriber'* – the general medical practitioner or specialist medical practitioner to whom the medicinal cannabis approval is granted
- *'patient-class prescriber'* – the specialist medical practitioner who is a member of a class of specialist medical practitioners prescribed by regulation to have an as-of-right authority to prescribe medicinal cannabis, subject to any stated limitations, and their registrar.
- *'patient'* – the person to whose treatment the medicinal cannabis approval applies
- *'dispensing pharmacy'* – the pharmacy or public hospital pharmacy stated in the medicinal cannabis approval as being where the medicinal cannabis will be dispensed

- *'carer'* – the adult responsible for the immediate care and safety of the patient
- *'dispensing approval'* – an approval granted to a pharmacist to dispense medicinal cannabis
- *'approved pharmacist'* – the pharmacist to whom a dispensing approval is granted, or a pharmacist who works in a hospital pharmacy
- *'secondary dispenser'* – the pharmacist stated in the dispensing approval as being the secondary dispenser, and authorised to dispense medicinal cannabis when the approved pharmacist is unavailable to do so
- '*restricted access patient'* – a patient not reasonably able to possess or self-administer medicinal cannabis due to their medical condition or location
- *'facilitator'* – a person who, because they have regular access to a restricted access patient, is authorised to possess, supply or administer medicinal cannabis to the patient
- *'responsible person'* - the person in charge of an institution (e.g. hospital, school, nursing home or prison) in which a restricted access patient is located
- *'medicinal cannabis management plan'* – a document detailing how the responsible person for an institution (or a single-patient prescriber or approved pharmacist, if this is a condition of their approval) will manage the risks associated with performing activities with medicinal cannabis
- *'authorised person'* – an inspector appointed under the proposed framework
- *'carrier'* – a person engaged by a single-patient prescriber, a patient, carer or the chief executive or authorised person, to transport and deliver medicinal cannabis
- *'expert advisory panel'* - the panel of experts providing advice and making recommendations to the chief executive
- *'clinical trial approval'* – an approval granted to facilitate a clinical trial using medicinal cannabis
- *'compliant medicinal cannabis'* – medicinal cannabis prescribed in accordance with the medicinal cannabis approval, and dispensed in accordance with the medicinal cannabis approval and the prescription.

Alternative ways of achieving policy objectives

There are no alternative ways of achieving the policy objectives as the use of medicinal cannabis needs to be strictly controlled and monitored through Queensland legislation in conjunction with Commonwealth legislation.

Unregulated therapeutic use of cannabis raises serious concerns, because the product used may have unknown concentrations of cannabinoids and may also contain potentially harmful contaminants. As such, the Queensland Government has decided to establish a tightly controlled regulatory framework allowing medicinal cannabis to be used where the potential benefits appear to outweigh the risks of unwanted side effects.

The case for action has been established and legislative reforms to facilitate access to medicinal cannabis are required, and therefore it is not a viable option for the government to take alternative action.

Estimated cost for government implementation

The cost of implementing the regulatory framework in the Bill will be met within existing budget allocations.

Consistency with fundamental legislative principles

Rights and liberties of individuals

Offences in the Bill duplicate offences in the *Drugs Misuse Act 1986* (DMA) to some extent.

The Bill makes it an offence to perform a regulated activity with medicinal cannabis unless authorised to do so under the Bill. The term 'regulated activity' includes prescribing, possessing, obtaining, manufacturing, supplying, administering or destroying medicinal cannabis. The penalty for the offence is 750 penalty units.

Under the DMA, the unlawful possession, supply, production and trafficking of a dangerous drug (which includes cannabis) are crimes. The penalties for these crimes range from 15 to 25 years imprisonment, depending on the amount of cannabis involved and the circumstances of the offence. These activities are done 'unlawfully' if not authorised, justified or excused by law.

An activity with medicinal cannabis not authorised under the Bill is an unlawful activity under the DMA.

This raises the issue of whether the legislation has sufficient regard to the rights and liberties of individuals, because the same factual circumstances may constitute an offence under the Bill and a crime under the DMA. Generally speaking, the imposition of liability under legislation should provide a single process for the liability, with all forms of double jeopardy being avoided as far as possible.

In this instance, the duplication of offence provisions in the Bill and the DMA is justified and will not unfairly impact on the rights and liberties of individuals.

The only persons under the Bill who may be granted approvals are medical practitioners and pharmacists (a patient lawfully possesses and administers medicinal cannabis as a consequence of the approvals granted to their treating practitioner and to the dispensing pharmacist). Medical practitioners and pharmacists are classes of persons that already occupy positions of high probity and responsibility, whose activities are not only governed by law, but also by the ethical and technical standards of their respective professional bodies.

It is thought the most likely contraventions under the Bill will occur where a medical practitioner or pharmacist fails to strictly comply with the narrow limits of their approval. For example, it would be an unauthorised regulated activity for a medical practitioner to prescribe a medicinal cannabis dosage for their patient that differs from the prescribed dosage noted on the medicinal cannabis approval. Another example of an unauthorised regulated activity would be a pharmacist storing medicinal cannabis at their pharmacy in a receptacle that did not comply with the security requirements for that receptacle, as noted on their dispensing approval.

In both examples, the activity with medicinal cannabis would not be authorised under the Bill because the activity did not comply with the relevant authorisation. As a result, these activities are not 'lawful' and would constitute crimes under the DMA.

However, the reasons for the non-compliance may not always be considered 'criminal'. In the case of the medical practitioner, the offence may simply have arisen from a treatment decision made in good faith, and for the pharmacist, the offence could be a technical oversight that may have no practical impact on the security of the medicinal cannabis at the pharmacy.

In such circumstances, the Queensland Police Service may elect not to initiate criminal proceedings against the medical practitioner or pharmacist pursuant to the DMA. Rather, it would be for Queensland Health to take compliance action under the Bill, if required.

For this reason, it is thought the Bill should contain offences to both deter non-compliance and enable appropriate enforcement action when warranted.

There may be instances where an unauthorised activity under the Bill is clearly 'criminal' behaviour - for example, where a patient, medical practitioner or pharmacist sells the medicinal cannabis to an authorised person for profit. If this were to occur, it is likely the Queensland Police Service would take the lead and initiate criminal proceedings.

It is acknowledged the ability for the same circumstances to give rise to offences under both the Bill and the DMA may cause some uncertainty about the possible prosecution action flowing from an unauthorised regulated activity under the Bill. Queensland Health will liaise with the Queensland Police Service prior to implementation of the Bill, to formalise processes for respective enforcement action in the event of an unauthorised use of medicinal cannabis. The public awareness campaign in support of the Bill will also include messaging that any use of cannabis not authorised under the Bill remains an offence under the DMA.

The Office of Queensland Parliamentary Counsel (OQPC) advised that the Bill does not raise any FLP issues likely to be of any real concern to a parliamentary committee, and most FLP issues raised at the Authority to Prepare stage have been addressed during drafting.

However, OQPC did note the Bill allows for the chief executive to conduct criminal history checks on applicants for approvals and on patients who will use medicinal cannabis under an approval. For the purpose of the criminal history check provisions, the *Criminal Law (Rehabilitation of Offenders) Act 1986*, does not apply. Therefore, spent convictions under that Act will still form part of a person's criminal history for the purpose of criminal history checks under the Bill. It is considered this is justified given the risk of diversion associated with the medicinal cannabis.

Consultation

Broad community consultation on the draft Bill was undertaken on 1 March 2016 to 1 April 2016 on the Queensland Government's *Get Involved* website. The consultation included a brief explanatory statement, a detailed discussion paper and a copy of the draft Bill.

Community members were invited to make a submission by completing an online survey with targeted questions. This approach assisted in managing and analysing the large volume of community feedback and ensured the consultation was focused on the key issues that shaped the regulatory framework.

The regulatory framework proposed in the Bill was clearly explained in the discussion paper. The discussion paper also provided additional contextual information about the regulation of medicinal cannabis.

In addition to the online survey, the department conducted targeted consultation with key health industry stakeholders, including one-on-one meetings, forums and working parties.

These stakeholders, particularly medical professionals in speciality areas for which medicinal cannabis treatment may be sought, and health care workers likely to be involved in delivering such treatment include the following:

- professional associations representing:
  - general practitioners, including those in rural practices
  - medical specialists, including those in relevant areas such as oncology, paediatrics, palliative care, psychiatry, neurology, research and HIV/AIDS
  - pharmacists
  - nurses, paramedics and carers
  - indigenous health workers
  - public and private hospitals
- universities
- Commonwealth agencies, including the TGA and those in relation to aged care, medical research, drug scheduling and customs
- drug and alcohol treatment services
- advocacy groups in support of medicinal cannabis.

The department also conducted targeted consultation with key government stakeholders:

- Department of the Premier and Cabinet
- Queensland Treasury
- Department of Justice and Attorney-General
- Department of Agriculture and Fisheries
- Department of Education and Training
- Department of Communities, Child Safety and Disability Services
- Queensland Family and Child Commission
- Queensland Police Service.

Representatives from most of these agencies were also members of an inter-department committee which provided advice to in relation the development of the policy and legislation.

Consistency with legislation of other jurisdictions

In all States and Territories in Australia, it is illegal to use, possess, cultivate, manufacture or sell cannabis. However, developments are occurring with respect to medicinal cannabis in a number of Australian jurisdictions.

To ensure a sustainable, legal supply of safe medicinal cannabis products for approved Australian patients, the Commonwealth recently passed amendments to the *Narcotic Drugs Act 1967* (Cwlth) to establish a scheme for the cultivation and manufacture of medicinal cannabis.

In New South Wales, initiatives involving the use of medicinal cannabis include a terminal illness cannabis scheme, which enables adults with a terminal illness to register to use and possess cannabis for therapeutic purposes. The Centre for Medicinal Cannabis Research and Innovation researches cannabis for therapeutic purposes, supports evidence-based innovation, and also monitors the clinical trials and educates the community.

The Victorian Government recently passed legislation to allow a limited cohort of patients access to treatment with certain medicinal cannabis products, and then establish an Office of Medicinal Cannabis to oversee the expansion of medicinal cannabis treatment to other patients, and using a wider range of products. The legislation also facilitates domestic cultivation and manufacture of medicinal cannabis, pursuant to the Commonwealth scheme.

Internationally, medicinal cannabis has been approved for use in many countries including Austria, Canada, the Czech Republic, Denmark, Germany, Israel, Italy, New Zealand, Spain, Sweden and the United States.

Notes on provisions

Chapter 1 Preliminary

1 Short title

Clause 1 provides that, when enacted, the short title of the Bill will be the *Public Health (Medicinal Cannabis) Act 2016.*

2 Commencement

Clause 2 provides for the commencement of the Bill, when enacted, to be on a day to be fixed by proclamation.

3 Act binds all persons

Clause 3 provides that the Bill, when enacted, will bind all persons including the State of Queensland and as far as the legislative power of the Parliament permits, the Commonwealth and other States. Nothing in the Bill makes the State, the Commonwealth or another State liable to be prosecuted for an offence against the Bill.

4 Object of Act

Clause 4 sets out the object of the Bill which is to provide regulated access to medicinal cannabis through a system of approvals by single-patient prescribers and also access through a system of prescription, without medicinal cannabis approvals, by patient-class prescribers.
A ***single-patient prescriber*** is a medical practitioner who holds an authority under this legislation to treat a particular patient with medicinal cannabis.
A ***patient-class prescriber*** is a specialist medical practitioner who is a member of a class of specialist medical practitioners prescribed by regulation and their registrar.

Chapter 2 Interpretation

5 Definitions

Clause 5 is the reference clause for the dictionary in schedule 1 which defines particular words used in the Bill.

6 Meaning of medicinal cannabis

Clause 6 provides the meaning of ***medicinal cannabis*** as being a cannabis product that is not an approved good and that is used or is intended to be used for human therapeutic purposes.

7 Meaning of cannabis product

Clause 7 provides the meaning of ***cannabis product*** as any product that is or was a part of, or derived from, the plant of the genus *Cannabis*, whether living or dead, or a product that is intended to have a substantially similar effect. Clause 7(c) ensures synthetic cannabis products will be included within the meaning of ***cannabis product*** for the purposes of the Bill. Clause 7(c) is not intended to apply more generally to other products that have some similar effects to cannabis or synthetic cannabis products.

8 References to particular terms relating to medicinal cannabis approvals

Clause 8 provides that if a particular provision applies to or in relation to a medicinal cannabis approval, references to the single-patient prescriber, the patient, the dispensing pharmacy and the medicinal cannabis are references to the single-patient prescriber that is the holder of the approval, the patient to whom the approval applies, the dispensing pharmacy stated in the approval and the medicinal cannabis that is the subject of the approval, respectively.

Chapter 3 Approvals

Part 1 Application for approvals

Division 1 Preliminary

9 Definitions for part

Clause 9 defines the meaning of certain words that are used in part 1:

- *application* means one or more of the following applications for an approval; an original application, an amendment application, a replacement application, and a renewal application (other than a renewal for medicinal cannabis approval or a clinical trial approval).
- *information requirement notice* means a notice given by the chief executive requiring information from the applicant to decide the application.

10 Suitability of person to hold approval

Clause 10 seeks to ensure only suitable people hold approvals. It does this by outlining the suitability of a person to hold, or continue to hold, an approval. The suitability matters the chief executive may give consideration to include, but are not limited to:

- qualifications and experience;
- character and standing;
- criminal history;
- whether the holder engages in conduct that would risk medicinal cannabis being used unlawfully; and
- the holder's knowledge and understanding of their legislated obligations.

11 Suitability of patient to undergo treatment with medicinal cannabis

Clause 11 seeks to ensure only specific patients have access to medicinal cannabis by outlining the matters the chief executive may consider when deciding if a patient is suitable to be treated with medicinal cannabis. The suitability matters the chief executive may give consideration to include, but are not limited to:

- the patient's personal circumstances
- the patient's criminal history;
- the advice of the expert advisory panel;
- the advice of a specialist medical practitioner; and
- whether the patient will be able to comply with the legislation and any conditions on the approval.

12 Approved form

Clause 12 requires that an application for approval (including an amendment, replacement or renewal) must be made in the approved form where required.

Division 2 Particular provisions for application for medicinal cannabis approval

13 Purpose of division

Clause 13 states that this division sets out the requirements for applying for a medicinal cannabis approval. In particular, this division outlines who may apply for a medicinal cannabis approval, the requirements for patient consent and the opinion of a specialist medical practitioner.

A medicinal cannabis approval is an approval given by the chief executive that allows a particular medical practitioner to treat a particular patient with medicinal cannabis.

14 Who may apply for medicinal cannabis approval

Clause 14 states that only a medical practitioner may apply for a medicinal cannabis approval to treat a specific patient with medicinal cannabis. The application must be made in accordance with clause 10 which sets out the suitability of a person to hold or continue to hold a medicinal cannabis approval. Each medicinal cannabis approval will be specific to one patient and the medical condition being treated and will set out requirements and any conditions imposed on that approval.

15 Requirements before making application for medicinal cannabis approval

Clause 15 states an applicant (being the medical practitioner) must not apply for a medicinal cannabis approval without the patient's (or person with authority to act on the patient's behalf) written consent to the treatment and also consent to the making of the application. This will help ensure approvals are given only when they are going to be used correctly and for the appropriate patient.

16 Opinion of specialist medical practitioner to accompany application

Clause 16 states if prior to making a medicinal cannabis application an applicant (being the medical practitioner) obtained a written opinion from a specialist medical practitioner in relation to the treatment of the patient with medicinal cannabis, a copy of the opinion must be included in the application.

Division 3 Particular provisions for application for dispensing approval

17 Purpose of division

Clause 17 sets out the requirements involved in applying for a dispensing approval. In particular, this division outlines who may apply for a dispensing approval.

A dispensing approval is an approval given by the chief executive that allows a pharmacist to dispense medicinal cannabis.

18 Who may apply for dispensing approval

Clause 18 states a pharmacist may apply for a dispensing approval. The application must be made in accordance with clause 10 which sets out the suitability of a person to hold or continue to hold a dispensing approval.

Division 4 Particular provisions for clinical trial approval

19 Purpose of division

Clause 19 sets out the requirements involved in applying for a clinical trial approval. In particular, this division outlines who may apply for a clinical trial approval.

A clinical trial approval is an approval given by the Department of Health chief executive to include medicinal cannabis in a clinical trial approved by the Commonwealth.

20 Who may apply for clinical trial approval

Clause 20 provides for a person to apply for a clinical trial approval. The application must be made in accordance with clause 10 which sets out the suitability of a person to hold or continue to hold a clinical trial approval.

Division 5 Process for deciding applications

21 Consideration by the expert advisory panel

Clause 21 allows the chief executive to provide information about an application to the expert advisory panel established under chapter 8.

22 Requirement to seek opinion of specialist medical practitioner

Clause 22 allows the chief executive to require an applicant to obtain and provide the opinion of a specialist medical practitioner as many times as is needed to help decide the application. Clause 16 relates to a specialist opinion obtained before the application process.

The provision of a specialist medical practitioner's opinion may be required to ensure that treatment with medicinal cannabis is appropriate in all the circumstances for which a patient is treated with a medicinal cannabis product. For example, if the applicant is a general practitioner, a specialist in the treatment and care of patients undergoing chemotherapy may be required to properly decide the application.

23 Decision on application for approval

Clause 23 provides for the chief executive to determine an application and sets out the notification requirements following the decision on an application.

Subclause (1) allows the chief executive to grant the application, grant the application subject to conditions or refuse to grant the application.

Subclause (2) requires the chief executive to give an applicant the applicable approval documentation when the application has been decided.

Subclause (3) requires the chief executive to give the approval holder notice of a request to return the approval if the approval is cancelled.

Subclause (4) requires the chief executive to give the applicant a notice as soon as practicable about a decision to refuse to grant an application or impose conditions on an approval.

This ensures the applicant is informed clearly and timely about the status and outcome of an application.

24 Criteria for grant of medicinal cannabis approval

Clause 24 sets out the criteria for granting a medicinal cannabis approval. It provides a list of matters that the chief executive may consider to assist in deciding whether or not to grant a medicinal cannabis approval. The clause gives the chief executive the power to consider any matters he or she considers relevant, but could include:

- the patient's medical condition and symptoms;
- the form and dosage of medicinal cannabis proposed;
- whether the proposed treatment can be integrated into the existing treatment;
- an opinion of a specialist medical practitioner;
- alternative treatments;
- the patient's history of drug dependence; and
- any other information included with the application.

There are three matters set out in subclause (2) that the chief executive must be satisfied of to grant a medicinal cannabis approval:

- that the applicant is a suitable person to hold the approval;
- that the patient is a suitable person to undergo the proposed treatment;
- that the medicinal cannabis has, or will be, manufactured or imported and is, or will be, able to be supplied as approved by the Commonwealth.

This provision seeks to ensure all relevant factors are carefully considered to ensure the use of medicinal cannabis is appropriate for the patient and their particular circumstances.

25 Criteria for grant or renewal of dispensing approval

Clause 25 sets out the criteria for granting or renewing a dispensing approval. It provides a list of matters that the chief executive may consider to assist in deciding a dispensing approval. The clause gives the chief executive the power to consider any matters he or she considers relevant, but could include:

- the applicant's familiarity with the use of medicinal cannabis for therapeutic purposes;
- the location and facilities of the pharmacy from which the medicinal cannabis will be dispensed; and
- any other information included with the application.

Subclause (2) sets out that the chief executive must be satisfied that the applicant is a suitable person to hold a dispensing approval before granting the approval.

This provision seeks to ensure all relevant factors are carefully considered to mitigate the risk of medicinal cannabis being dispensed, supplied or issued inappropriately.

26 Criteria for grant of clinical trial approval

Clause 26 sets out the criteria for granting a clinical trial approval. It provides a list of matters that the chief executive may consider to assist in deciding an application for a clinical trial approval. The clause gives the chief executive the power to consider any matters he or she considers relevant, but could include any approval required for the trial under Commonwealth law or any other information included with the application.

However, there are two matters set out in subclause (2) that the chief executive must be satisfied of before granting a clinical trial approval:

- that the applicant is a suitable person to hold the approval; and
- that the medicinal cannabis has, or will be, manufactured or imported and is, or will be, able to be supplied as approved by the Commonwealth.

This provision seeks to ensure all relevant factors are carefully considered to ensure medicinal cannabis is used appropriately and only for approved and relevant clinical trials.

27 Chief executive may require information or documents

Clause 27 allows the chief executive to gather further information or evidence to assist in deciding an application for an approval by investigating the applicant or, for a medicinal cannabis approval - investigating the patient, or requesting further information from the applicant by means of an information requirement notice which states the information required to decide the application.

The information requirement notice must be given to the applicant within 14 days for a renewal application or within 60 days for another application after the chief executive receives the application.

The information requirement notice must state a reasonable period for compliance with the notice, which is at least 14 days for a renewal application and at least 30 days for another application.

The information required must be verified by statutory declaration if it is required by the information requirement notice.

The application will be deemed withdrawn if the applicant fails to comply with the information requirement notice.

28 Criminal history report

Clause 28 allows the chief executive to request a criminal history report from the commissioner of police to ensure only the appropriate people are able to hold an approval relating to medicinal cannabis.

Subclause (1) allows the chief executive to ask the commissioner for a written criminal history report for an applicant for an approval, or a patient for a medicinal cannabis approval. In order to ensure a person continues to be a suitable person to hold an approval, the chief executive may request a further criminal history check if it is known or suspected that the person has been convicted of an offence in relation to the relevant approval.

Subclause (2) allows the chief executive to also ask for a brief description of the circumstances of a conviction or charge in the individual's criminal history report.

Subclause (3) allows the chief executive to request the individual's name and any other name that the individual uses or may have used, their residential address, sex and the date and place of their birth.

Subclause (4) allows the chief executive to request further information about the individual's criminal history upon receiving their written criminal history report.

Subclause (5) states that all information requested under subclause (4) will become part of the individual's criminal history check.

Subclause (6) provides that the commissioner must comply with a request made under this section however it is subject to subclause (7).

Subclause (7) states the commissioner's obligation to comply with the request only applies to information for which the commissioner possesses or can access.

29 Individuals for whom criminal history checks may be conducted

Clause 29 prescribes the list of individuals for whom criminal history checks may be conducted.

Subclause (1) allows the chief executive to conduct a criminal history check of the applicant, the patient, or either the approval holder or the patient who the chief executive knows, or reasonably suspects has been convicted of an offence.

This clause seeks to ensure only suitable persons hold or continue to hold approvals and that patients are suitable and continue to be suitable, to be treated with medicinal cannabis. A regulation may prescribe a fee for a criminal history check.

30 Commissioner of police must notify changes in criminal history

Clause 30 provides that the commissioner must notify the chief executive about any changes to the individual's criminal history and the notice must state individual's name and address, date of birth, the offence the individual is charged with, particulars of the offence and the date of the charge.

31 Application of *Criminal Law (Rehabilitation of Offenders) Act 1986*

Clause 31 provides that the *Criminal Law (Rehabilitation of Offenders) Act 1986* does not apply to a request, disclosure or notification for criminal history under this division. This means spent convictions under that Act will still form part of a person's criminal history for the purpose of criminal history checks under the Bill.

32 Chief executive may extend period for decision for complex application

Clause 32 allows the chief executive to extend the period for deciding an application for an approval if there are complex matters to be considered for the application. The chief executive must give the applicant notice of the days extended.

33 Failure to decide application

Clause 33 provides when an application is considered to be refused.

Subclause (1) provides that an application is considered refused if the chief executive fails to approve the original application within 90 days, the renewal application within 30 days or another application within 60 days of receiving the application.

Subclause (2) provides that a period mentioned in subclause (1) starts from the day the chief executive receives the information required from an applicant in response to the information requirement notice.

Subclause (3) provides that an application is considered refused if the chief executive has extended the period to decide the application and does not approve the application within the extended period.

Subclause (4) provides that an application is considered refused if the chief executive gives the applicant an information notice for the application to be deemed refused.

Part 2 Grant of approvals

Division 1 Grant of approvals generally

34 Standard conditions for approvals

Clause 34 states that the standard conditions for approving medicinal cannabis for a clinical trial may be prescribed by regulation. The clause also allows the regulation to prescribe the conditions by way of a code, guideline, protocol or standard.

35 Additional or varied conditions for approvals

Clause 35 provides that the chief executive may impose additional conditions or vary standard conditions on an approval where it is reasonably believed to be necessary.

36 Term of approvals

Clause 36 provides that any approvals, other than a clinical trial approval, remain in force for the period no more than 1 year unless the chief executive has stated otherwise for it be cancelled sooner, suspended or surrendered.

37 Transfer of approvals prohibited

Clause 37 prohibits the transfer of an approval.

Division 2 Form of medicinal cannabis approval

38 Form of medicinal cannabis approval

Clause 38 provides that a medicinal cannabis approval must be in the approved form and contain specific information:

- the single-patient prescriber's name and qualifications;
- the name and address of the business where the single-patient prescriber practises medicine;
- the name, address and date of birth of the patient;
- the term of the approval;
- the conditions applying to the approval;

- details of the TGA approval; and
- the name and address of the dispensing pharmacy for the approval.

Division 3 Form of dispensing approval

39 Form of dispensing approval

Clause 39 provides that a dispensing approval must be in the approved form and contain specific information:

- the approved pharmacist's name and qualifications;
- the name and business address of the pharmacy where the medicinal cannabis will be dispensed;
- the name, qualifications and address of any secondary dispenser;
- the term of the approval; and
- the conditions applying to the approval.

Division 4 Form of clinical trial approval

40 Form of clinical trial approval

Clause 40 provides that a clinical trial approval must be in the approved form and contain specific information:

- the approval holder's name and qualifications;
- details of the approval of the trial by the Commonwealth or an ethics committee;
- the term of the approval; and
- the conditions applying to the approval.

41 Term of clinical trial approval

Clause 41 provides that a clinical trial approval remains in force for the term approved unless the chief executive has stated otherwise for it be sooner cancelled, suspended or surrendered.

Part 3 Amendment, replacement and renewal of approvals

Division 1 Preliminary

42 Making applications

Clause 42 provides that an application to amend, replace or renew an approval must be made to the chief executive in the approved form.

43 Process for deciding application

Clause 43 provides that the process for deciding an application to amend, replace or renew an approval must be done in accordance with part 1, division 5 (Process for deciding applications).

Division 2 Amendment

44 Application by holder to amend approval

Clause 44 provides that an approval holder may apply to the chief executive to amend their approval about the things that are authorised under the approval, the use of medicinal cannabis for treatment, and the conditions that apply to the approval. This will give the flexibility needed if, for example, the treatment dosage for a patient needs adjustment to align with changes in their condition.

45 Minor amendment of approval by chief executive

Clause 45 allows the chief executive to make minor and administrative amendments to an approval.

Subclause (1) allows the chief executive to amend the approval for a formal or clerical reason or for another reason where the chief executive reasonably believes that the amendment will not adversely affect the interests of a person to whom the approval applies.

Subclause (2) states that the chief executive must give notice to the person as soon as possible if the chief executive decides to amend the approval. The notice must state what the amendment is and the reason for it. The approval holder must return the approval to the chief executive for endorsement if necessary.

Division 3 Replacement

46 Application for replacement of approval

Clause 46 provides that the holder of the approval may apply to replace the approval if the instrument for the approval has been damaged, destroyed, lost or stolen.

47 Criteria for deciding replacement application

Clause 47 allows the chief executive to approve to replace the instrument for the approval if the chief executive reasonably believes that the approval has been damaged, destroyed, lost or stolen.

Division 4 Renewal

48 Application for renewal of dispensing approval

Clause 48 provides that the holder of a dispensing approval may apply to the chief executive to renew their approval.

Subclause (1) provides the application to renew the approval must happen within 60 days before term of the approval ends.

Subclause (2) allows the chief executive to accept renewal application within 30 days after the term of the approval ends if the chief executive believes that it is reasonable to do so in the circumstances.

49 Dispensing approval taken to be in force while renewal application considered

Clause 49 provides for continuity of access for patient treatment, even where a dispensing approval is due for renewal.

The clause provides that an approval continues in force if it is subject to a renewal application until it has been withdrawn or decided. If the renewal application is subsequently refused, the approval continues in force until an information notice is given for the refusal. This does not stop an approval being suspended or cancelled while it is subject to a renewal application.

Part 4 Return and surrender of approvals

50 Return of instrument of approval

Clause 50 states that an approval holder must return and surrender an original instrument for an approval if required by the chief executive or if they have a replacement instrument and find the original, within 7 days after receiving the requirement or as soon as practical after finding the original.

Chapter 4 Dealings with medicinal cannabis

Part 1 Preliminary

51 Authority subject to Act and approval

Clause 51 clarifies that a person authorised to perform an activity under this chapter but only in accordance with this Bill or any conditions or restrictions imposed on an authority itself or conditions or restrictions imposed under a regulation.

Part 2 Medicinal cannabis prescribed by patient-class prescribers

At the time of the Bill's introduction, cannabis is classed as a schedule 9 under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which prohibits substances being used for a therapeutic purpose.

Dronabinol, nabilone and nabiximols are the only medicinal cannabis products already classed as schedule 8 under the SUSMP, and are subject to specific controls due to their composition and high illicit value.

Nabiximols is the only medicinal cannabis product that has been registered on the Australian Register of Therapeutic Goods (ARTG).

The Commonwealth intends to re-schedule S9 cannabis products to S8 where the product is botanical (or botanically-derived) and prepared or packed for human therapeutic use. For this reason, and to take best advantage of re-scheduling should it occur, the Bill includes a mechanism by which particular specialist medical practitioners may prescribe cannabis to certain patients without the need to obtain a medicinal cannabis approval.

52 Prescription of medicinal cannabis other than under medicinal cannabis approval

Clause 52 provides a head of power for a regulation to prescribe a class of specialist medical practitioners who may prescribe medicinal cannabis and the conditions under which they may prescribe.

The clause also allows a regulation to prescribe a class of patients who may be prescribed medicinal cannabis and the type of medicinal cannabis that may be prescribed.

The regulation may require the prescribed class of specialist medical practitioner to comply with a code, guideline, protocol or standard or to notify the chief executive if a particular thing happens. This does not limit the regulation being able to prescribe the type of medicinal cannabis that can be prescribed.

53 Patient-class prescribers

Clause 53 allows a patient-class prescriber, if satisfied it is proper under this Bill, to give a lawful direction for the issue or supply of eligible medicinal cannabis for the purpose of treating their patient or to administer eligible medicinal cannabis to the patient. The prescriber may also obtain and possess the medicinal cannabis until the patient can be treated and only for the purpose of treating the person. If necessary, the prescriber may administer the medicinal cannabis to the patient

54 Eligible patients

Clause 54 allows a patient to obtain, possess or self-administer compliant medicinal cannabis in accordance with a lawful direction. The patient is also authorised to issue the medicinal cannabis the patient-class prescriber for the purpose of administering the medicinal cannabis to the patient, a carer or a facilitator or responsible person for a facility.

55 Carers

Clause 55 allows a carer to obtain and possess eligible medicinal cannabis until the patient they are caring for is treated and only for the purpose of the treatment. The carer is authorised to supply the medicinal cannabis to the patient, administer the medicinal cannabis or issue it to a patient-class prescriber, facilitator or responsible person for a facility.

56 Approved pharmacists and secondary dispensers

Clause 56 provides that an approved pharmacist is authorised to obtain and possess eligible medicinal cannabis for the purpose of selling, supplying or issuing the product to a patient or carer or other persons authorised for that product.

Subclause 2(b) allows the pharmacist to assemble, label, pack, repack, store and sterilise medicinal cannabis.

Subclause 3 authorises a secondary dispenser under the dispensing approval to possess, supply and issue medicinal cannabis when the approved pharmacist is not present at the dispensing pharmacy.

Part 3 Medicinal cannabis prescribed under medicinal cannabis approvals

57 Single-patient prescribers

Clause 57 outlines that a single-patient prescriber is a person who is authorised to give a direction, instruction or prescription about the issue, supply or administration of medicinal cannabis to a patient. The single-patient prescriber is permitted to obtain or possess the medicinal cannabis until the patient can be treated with it and only for the purpose of the treatment.

58 Approved pharmacists and secondary dispensers

Clause 58 provides that an approved pharmacist is authorised to obtain and possess a medicinal cannabis product for the purpose of supplying or issuing the product to a patient or carer for a medicinal cannabis approval for that product.

Subclause 2(b) allows the pharmacist to assemble, label, pack, repack, store and sterilise medicinal cannabis.

Subclause 3 authorises a secondary dispenser under the dispensing approval to possess, sell, supply and issue medicinal cannabis when the approved pharmacist is not present at the dispensing pharmacy.

59 Patients

Clause 59 provides that the patient for a medicinal cannabis approval is authorised to obtain, possess or self-administer or issue complaint medicinal cannabis to the single-patient prescriber, the carer, facilitator or a responsible person for an institution.

60 Carers

Clause 60 provides the carer of a patient is authorised to obtain and possess medicinal cannabis until the patient can be treated and only for the purpose of treating the patient. The carer is authorised to supply or administer the medicinal cannabis to the patient or issue it to the single-patient prescriber or facilitator or person responsible for an institution.

Part 4 General provisions

61 Restricted access patients

Clause 61 provides a way for a patient to use medicinal cannabis if they are not able to self-administer, or if the carer is not able to administer the medicinal cannabis.

The clause provides that if a patient's age, medical condition or location prohibit a patient from obtaining, possessing or self-administering medicinal cannabis or their carer is not able to administer or supply medicinal cannabis, another person who is an adult and has regular access to the patient can obtain and possess medicinal cannabis unto the patient can be treated and only for the purpose of treating the patient. The person may supply, issue or administer the medicinal cannabis to the patient.

If the patient is in an institution, the person in charge of the institution may obtain or possess medicinal cannabis at the institution while the patient is there. The person in charge may also

issue the medicinal cannabis to the person who is an adult and has regular access to the patient for the purpose of treating the patient.

The clause also provides a head of power for a regulation to prescribe conditions for the administration of medicinal cannabis to a restricted access patient.

The terms ***controlled drug***, ***out-of-home care service***, ***prescribed person*** and ***responsible person*** are defined for the clause.

62 Carriers

Clause 62 provides for the transportation and delivery of medicinal cannabis products. The intent of the provision is to authorise a person such as a carer or a courier and an employee of a courier to transport, possess and store cannabis, cannabis extract or a medicinal cannabis product when engaged by a person who is authorised to transport in respect of that cannabis.

63 Authorised persons

Clause 63 allows an authorised person to obtain, possess and to destroy medicinal cannabis in order to perform their official functions. Clause 100 lists these functions as:

- investigation, monitoring and enforcing compliance;
- investigating or monitoring whether an occasion has arisen for the exercise of powers;
- facilitating the exercise of powers.

64 State analysts

Clause 64 allows a State analyst appointed under the *Health Act 1937* or a trainee State analyst to obtain, possess, use or destroy medicinal cannabis to perform their official duties.

65 State forensic and scientific service facilities

Clause 65 allows the person in charge, or an appropriately qualified officer, of a forensic and scientific facility operated by the State to possess or destroy medicinal cannabis.

66 Approved clinical trials

Clause 66 provides that a person can possess, obtain, dispense, issue, supply, sell, administer or self-administer medicinal cannabis for an approved clinical trial. A medical practitioner can give a direction, instruction or prescription for medical cannabis for a trial.

These authorities can only be exercised for the carrying out of the trial, for the purpose of treating a patient taking part in the trial and in accordance with the clinical trial approval and Commonwealth approval.

67 Use of instruments or things to administer medicinal cannabis

Clause 67 provides for the use of instruments or things used to administer and self-administer medicinal cannabis.

68 Regulation may prescribe authority

Clause 68 provides that a regulation may prescribe authority to an eligible person to deal with medicinal cannabis in a way and subject to any conditions prescribed by the regulation.

This provision provides a list of persons to be classed as eligible persons and states that the eligible person may comply with a stated code, guidelines or standards and notify the chief executive if particular things happen. The term ***Hospital and Health Service*** is also defined.

Chapter 5 Managing medicinal cannabis

Part 1 Medicinal cannabis management plans

69 What is a medicinal cannabis management plan

Clause 69 defines a medicinal cannabis management plan as being a plan for managing the known and foreseeable risks associated with an activity that involves medicinal cannabis that an entity is authorised to perform.

70 What must be included in plan

Clause 70 states what must be included in a medicinal cannabis management plan. This provision provides the list of information requirements, the way the plan must be written, the relevant activity performed by the entity and any additional matters that will be dealt with under the plan.

The clause also contains a head of power for a regulation to prescribe additional matters which could include the minimum standards or performance indicators to deliver particular risk management outcomes.

71 Who must make plan

Clause 71 provides who must make a medicinal cannabis management plan - being a single-patient prescriber, an approved pharmacist and a responsible person for an institution. A patient-class prescriber administering medical cannabis under chapter 4, part 2 must also make a medicinal cannabis plan.

The clause also provides a head of power for a regulation to prescribe additional entities that must make a medicinal cannabis management plan.

72 Making and notifying plan

Clause 72 sets a penalty of a maximum of 500 penalty units if a medicinal cannabis management plan is not prepared before an activity for which the plan relates is performed.

Once the plan is prepared, the chief executive must be notified about when the plan starts and when the activity dealt with by the plan will be performed for the first time – failure to do this attracts a penalty of a maximum of 50 penalty units.

73 Persons to be informed of plan

Clause 73 states that those entities responsible for medicinal cannabis management plan must take reasonable steps to inform persons to whom the plan applies and ensure that they comply with the plan. This provision states that the non-compliance will cost maximum penalty of 200 units.

74 Review of plan

Clause 74 states that an entity must review their cannabis management plan in accordance with the terms of the plan, in accordance with any requirements prescribed by a regulation and not more than 5 years after the day the plan starts. Failure to do so attracts a maximum fee of 200 penalty units.

75 Offence for failure to comply with plan

Clause 75 provides that a person must comply with the cannabis management plan unless they have a reasonable excuse. The non-compliance will attract a maximum penalty of 100 units.

Subclause (2) provides that for a defence against an offence of non-compliance, a person must prove that they were not informed about the contents of the medicinal cannabis management plan or they took all reasonable steps to comply with the plan.

Part 2 Administrative action

76 Definitions for part

Clause 76 defines *administrative action* as being the suspension, cancellation, variation or the imposition of conditions on a medicinal cannabis approval, dispensing approval or a clinical trial approval.

77 Grounds for action to be taken

Clause 77 empowers the chief executive to take administrative action in relation to a medicinal cannabis approval, dispensing approval or a clinical trial approval.

The administrative action (as defined in clause 76) may be suspension, cancellation, variation, or the imposition of conditions on the approval. The action will be taken against the holder of the approval.

The grounds for taking administrative action for all approvals are as follows:

- the holder of the approval has contravened the Bill or a condition of the approval;
- the welfare of a patient for a medicinal cannabis approval is at risk or the patient or their carer has contravened the Bill or a condition of the approval;
- the action is necessary to minimise the risk of the medicinal cannabis being dispensed, supplied or issued to an unauthorised person;
- the action is necessary to minimise a risk of harm to the life, health or safety of a person;
- the holder of the authority is not, or is no longer, eligible or suitable to hold the authority; or
- for a medicinal cannabis approval – the patient is not, or no longer, suitable to undergo treatment with medicinal cannabis;
- the approval was granted on a materially false or misleading representation or declaration.

78 Show cause notice

Clause 78 requires the chief executive to give the approval holder a show cause notice if the chief executive reasonably believes a ground exists to take administrative action. A show cause notice can only be given after the approval holder has been given a compliance notice about the ground and has failed to comply with the notice or there is no intention to give the holder a compliance notice about the ground.

The show cause notice must state the following:

- the administrative action the chief executive proposes to take;

- the grounds for the proposed action;
- an outline of the facts and circumstances forming the basis for the grounds;
- for a suspension - the proposed suspension period;
- for a variation - details of the variation;
- for imposition of conditions - details of the conditions;
- an invitation to show within a stated show cause period why the proposed action should not be taken.

The show cause period must be at least 21 days after the show cause notice is given to the approval holder.

79 Representations about show cause notices

Clause 79 states that a holder of an approval may make written representations to the chief executive about a show cause notice within the stated show cause period. The chief executive must consider all written representations.

80 Ending show cause process without further action

Clause 80 provides for the chief executive to end the show cause process if after considering the accepted representations from the holder of the approval, a ground no longer exists to take the proposed administrative action. The chief executive must give the holder written notice that no further action is to be taken about the show cause notice.

81 Decision to take administrative action

Clause 81 states that if after considering any representations, the chief executive still believes a ground exists to take the administrative action and also believes the action is warranted, the chief executive may make the following decisions:

- for a suspension - suspend the approval for no longer than the period stated in the show cause notice;
- for a cancellation - either cancel the approval or suspend it for a period;
- for a variation - either vary the approval as proposed in the show cause notice or impose a less onerous variation; or
- for imposition of conditions - either impose the conditions proposed in the show cause notice or impose less onerous conditions.

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 will then take effect on the day this notice is given to the holder, or if a later day of effect is stated in the notice, that later day.

This clause also applies if there were no written representations from the holder of an approval about a show cause notice.

82 Immediate administrative action

Clause 82 states that if the chief executive believes a ground exists to take administrative action, and also believes there is immediate and serious risk to the life, health or safety of a person, the chief executive may decide to immediately take action.

The action will take effect when the chief executive gives the approval holder an information notice and a show cause notice. The action continues to operate until the chief executive decides to cancel the action, the show cause notice is finally dealt with, or 60 days pass since the notices were given, whichever occurs first.

83 Additional power for immediate amendment or cancellation of medicinal cannabis approval

Clause 83 states that the chief executive may decide to amend a medicinal cannabis approval immediately if the amendment is necessary in the circumstances or the expert advisory panel recommends the immediate amendment.

The chief executive may also cancel a medicinal cannabis approval immediately if the approval holder has ceased to treat the person to whom the approval relates, and it is reasonably necessary, for the welfare of that person or class of persons, to urgently give an approval to someone else. The chief executive may be satisfied treatment has ceased, regardless of why treatment ceased or when the person was last treated.

The amendment or cancellation will take effect immediately upon the chief executive giving the approval holder an information notice, or on the day stated in the notice, whichever occurs first.

84 Chief executive to give notice of administrative action to boards

Clause 84 provides that if the chief executive takes administrative action in relation to a medicinal cannabis approval, a dispensing approval or a clinical trial approval and the approval holder's profession has a registered board, the chief executive must give written notice about the administrative action to that board as soon as practicable.

85 Chief executive may inform boards about particular matters

Clause 85 provides that further to clause 84, the chief executive may give information to an approval holder's or patient-class prescriber's professional board if the chief executive believes the holder has committed an offence against the Bill or a ground exists to take administrative action.

Part 3 Compliance notices

86 Giving a compliance notice

Clause 86 empowers the chief executive or an authorised person to issue a person with a compliance notice if they reasonably believe the following:

- the person has contravened a provision of the Bill or a condition of an approval and it is likely this contravention will continue or be repeated; and
- a matter relating to the contravention is reasonably capable of being rectified; and
- it is appropriate to give the contravener an opportunity to rectify the matter.

87 Content of compliance notice

Clause 87 sets out the content of the compliance notice to include:

- it is believed the person has contravened a provision of this Bill or a condition of an approval in circumstances that make it likely the contravention will continue or be repeated;

- the provision or condition the subject of the contravention;
- how it is believed the provision or condition has been contravened;
- how it is believed the contravention can be rectified;
- the reasonable steps that could be taken to rectify the matter;
- that the contravener must take the steps within a stated period, having regard to any life, health and safety risks posed (in addition for a medicinal cannabis approval – any risk of the medicinal cannabis being dispensed, supplied or issued to a person not authorised);
- that it is an offence not to comply with the compliance notice unless there is a reasonable excuse.

Part 4 Medicinal cannabis register

88 Chief executive to keep register

Clause 88 requires the chief executive to keep a register of approvals and administrative actions taken in relation to persons who hold, or have held, approvals.

89 Content of register—approvals

Clause 89 sets out the information to be contained in the register for each approval. The register must contain the following:

- any identification number allocated to the approval;
- the name of the approval holder;
- the type of approval;
- the term of the approval; and
- the conditions applying to the approval.

For a medicinal cannabis approval register, there is specific information be included on that register:

- the patient;
- the dispensing pharmacy.

Also for a dispensing approval, there is one extra and specific requirement – the name of any secondary dispenser.

90 Content of register—administrative action

Clause 90 states that for each person to whom administrative action has been taken, the register must contain the name of the person and a general description of the administrative action taken in relation to the person.

91 Register not to be made public

Clause 91 prohibits the register from being made public however, if asked by the commissioner of the police service, the chief executive may give the commissioner information contained in the register.

Chapter 6 Offences

92 Offence to perform regulated activities for medicinal cannabis

Clause 92 clarifies the policy intention to retain the unlawfulness of possessing, obtaining, manufacturing, dispensing, issuing, supplying, selling, or administering cannabis (a regulated activity) even if it is classed as medicinal cannabis except under the intention of this Bill.

The clause creates an offence of a maximum of 750 penalty units if a person performs, or attempts to perform, or agrees or offers to perform, a regulated activity for medicinal cannabis. However, the offence does not apply to a person who is authorised under this Bill to perform the regulated activity, or if the regulated activity is manufacturing medicinal cannabis under a law of the Commonwealth or if the person has a reasonable excuse.

The quantity of the medicinal cannabis or if two persons involved in an interaction are in the same place at the same time or they've interacted by indirect means (e.g. email. telephone, vending machine) is immaterial for the offence.

The clause also makes it clear a person authorised to possess medicinal cannabis commits an offence if they perform any regulated activity in relation to any other form of cannabis (i.e. not medicinal cannabis).

93 Misuse of lawful direction for medicinal cannabis

Clause 93 sets the offences for misusing a lawful direction for the use of medicinal cannabis, which includes a prescription or an instruction on a label or other packaging.

The clause creates an offence of a maximum of 100 penalty units if a person obtains or attempts to obtain, medicinal cannabis by using:

- a document they have prepared if they are not a single-patient prescriber or patient-class prescriber;
- a document they know has been prepared by a person who is not an approved single-patient prescriber or patient-class prescriber;
- a direction relating to the medicinal cannabis they know falsely states the name or address of the patient to be treated with the medicinal cannabis;
- a direction they know has been changed in any way other than by the single-patient prescriber, approved patient-class prescriber or approved pharmacist.

The clause also sets a penalty of a maximum of 100 penalty units if a single-patient prescriber or patient-class prescriber prepares a direction for medicinal cannabis in their own name, unless they have a reasonable excuse.

It also sets a penalty of a maximum of 100 penalty units if a person changes a direction in any way unless the person is the single-patient prescriber or a pharmacist authorised to dispense medicinal cannabis. However, a person does not commit this offence if the change was made accidently and the person takes reasonable steps to rectify the change.

94 Offence for false or misleading statements or documents

Clause 94 sets an offence of a maximum of 50 penalty units if a person gives a false or misleading statement or document in relation to:

- an application for an approval;

- an application for an amendment, replacement or renewal of an approval;
- a response to a request for information from the chief executive; or
- the purpose of obtaining a lawful direction for the use of medicinal cannabis, which includes a prescription or an instruction on a label or other packaging.

95 Offence for failure to comply with approval conditions

Clause 95 sets a penalty of a maximum of 200 penalty units if a person does not comply with conditions of an approval that apply to that person unless they have a reasonable excuse.

96 Offence for failure to comply with compliance notice

Clause 96 sets a penalty of a maximum of 200 penalty units if a person does not comply with a compliance notice given under chapter 5, part 3, unless they have a reasonable excuse.

97 Offence for failure to comply with recall order

Clause 97 sets a penalty of a maximum of 500 penalty units if a person does not comply with the requirements of a recall order made under chapter 7, part 6, division 1 unless they have a reasonable excuse.

98 State officers not liable for an offence

Clause 98 provides that:

- an authorised person under the Bill;
- a State analyst or trainee State analyst;
- a person employed or engaged by a forensic and scientific facility operated by the State; or
- a person authorised by another law to deal with medicinal cannabis;

is not liable for an offence for act done or omission made, honestly and without negligence while performing functions and exercising powers and responsibilities under this Bill.

Chapter 7 Monitoring, investigations and enforcement

Part 1 General provisions about authorised persons

Division 1 Appointment of authorised persons

99 Authorised persons under chapter

Clause 99 states that this chapter provides for the appointment of authorised persons and gives authorised persons particular powers. This chapter provides the necessary checks and balances and powers to minimise misuse and the risk of the medicinal cannabis being dispensed, supplied or issued to an unauthorised person.

100 Functions of authorised persons

Clause 100 prescribes the functions of an authorised person, as follows:

- to investigate, monitor and enforce compliance with the legislation; and
- to investigate or monitor whether powers under the legislation should be exercised, and then facilitate the exercise of those powers if needed.

101 Appointment and qualifications

Clause 101 empowers the chief executive to appoint, in writing, a public service employee or a person prescribed by a regulation as an authorised persons.

The chief executive may appoint a person, as an authorised person only if satisfied the person is appropriately qualified. To determine whether a person is appropriately qualified, the person's experience and expertise may be taken into account.

102 Appointment conditions and limit on powers

Clause 102 states that an authorised person's appointment may be subject to conditions and that the instrument of the appointment may place limitations on the authorised person's powers. The conditions will be stated on the instrument of appointment, a signed notice given to the authorised person or in a regulation.

103 When office ends

Clause 103 states the ways in which the office of an authorised person ends, including:

- the term of office specified in the conditions under which the person holds office ends;
- another condition under which the person holds office ends; or
- the person's resignation takes effect (see clause 104).

104 Resignation

Clause 104 states an authorised person may resign from being an authorised person by written notice to the chief executive.

Division 2 Identity cards

105 Issue of identity card

Clause 105 requires the chief executive to issue an identity card to each authorised person. The identity card must contain a recent photo of the authorised person, a copy of the authorised person's signature and identify the person as an authorised person. The card must have an expiry date.

106 Production or display of identity card

Clause 106 requires an authorised person to produce or display the authorised person's identity card if exercising a power in relation to another person. The card must be produced or displayed in the other person's presence. However, if it is not practicable in the circumstances to do so before exercising the power, the identification must be produced as soon as is practicable.

An authorised person does not exercise a power in relation to another person only because the authorised person enters a public place that is open to the public.

107 Return of identity card

Clause 107 states that it is an offence (with a maximum penalty of 20 penalty units) if an authorised person fails to return the person's identity card to the chief executive within 21 days of ceasing to be an authorised person.

Division 3 Preliminary

108 References to exercise of powers

Clause 108 states that if a provision of chapter 7 refers to the exercise of powers by an authorised person and there is no reference to a specific power, the reference is to the exercise of all or any powers of an authorised person under the chapter or a warrant, to the extent that the powers are relevant.

109 Reference to document includes reference to reproductions from electronic document

Clause 109 states that a reference to a document in the chapter includes reference to an image or writing produced from an electronic document or an image or writing capable of being produced with or without aid of another article or device.

Part 2 Entry of places by authorised persons

Division 1 Power to enter

110 General power to enter places

Clause 110 states under what circumstances an authorised person may enter a place. Entry may be made with consent from the occupier provided that the authorised person has given the occupier a reasonable explanation about the purpose of entry and the powers intended to be exercised. The occupier must also be advised that they are not required to consent and that consent may be given subject to conditions and may be withdrawn at any time. An authorised person may also enter a place if the place:

- is a public place and entry is made when the place is open to the public;
- if entry is authorised under a warrant and the entry procedure under clause 122 has been complied with;
- if the place is a dispensing pharmacy or place where a single-patient prescriber or patient-class prescriber practices medicine and is open for carrying on the business or otherwise open for entry or is required to be open for inspection under the authority; or
- if the entry is to check compliance with a compliance notice or recall order.

Subclause (2) prohibits entry to a person's residence unless entry is made with consent or under a warrant. Where entry is made by consent, the power of entry is subject to any conditions of the consent. The power ceases if consent is withdrawn.

Consent may be given for re-entry and is subject to the terms of consent. If a warrant provides power to enter or re-enter a place, the entry or re-entry is subject to the terms of the warrant.

Public place is defined as a place or part of a place the public is entitled to use, is open to members of the public or is used by the public regardless of whether or not a payment of money has been made. Examples include a road, a beach or a park. A ***public place*** is also a place or part of a place which the occupier allows members of the public to enter irrespective of whether or not there is payment of money. Examples include a showground, a shopping

centre or a theme park. A ***public place*** may also be a public place as defined under another Act.

111 Power to enter place to check compliance with notice or order

Clause 111 empowers an authorised person to enter a place, at reasonable times, to check compliance with a compliance notice or recall order. This power is subject to the procedural requirements of clause 110(2) (Entry to a place does not include entry to a part of the place where a person resides without the person's consent or a warrant) and clause 116 (Obtaining the occupier's consent or entry under a warrant).

Division 2 Entry by consent

112 Application of division

Clause 112 states that this division applies to circumstances where an authorised person intends to ask an occupier for consent for the authorised person or another authorised person to enter the place.

113 Incidental entry to ask for access

Clause 113 states the circumstances under which it is appropriate for an authorised person to enter a place without the occupier's consent or a warrant. Entry is permissible to land around premises at a place to the extent that it is reasonable to contact the occupier, or to that part of the place which the authorised person considers members of the public ordinarily are allowed to enter when they wish to contact the occupier.

114 Matters authorised person must tell occupier

Clause 114 states what information the authorised person must give the occupier prior to asking for consent to entry. The authorised person must explain the purpose of the entry, including the powers intended to be exercised and advise the occupier they are not required to consent and that consent may be given subject to conditions and may be withdrawn at any time.

115 Consent acknowledgement

Clause 115 states that if consent to entry is given, the authorised person may ask the occupier to sign a written acknowledgement of the occupier's consent. An acknowledgement must state the purpose of the entry, including powers to be exercised, that the occupier is not required to consent and that the consent may be subject to conditions which may be withdrawn at any time. The acknowledgement must also state that the occupier gives consent to enter the place and exercise powers, the time and day consent was given and any conditions of consent.

If the occupier signs the consent, a copy must be immediately given to the occupier. In a proceeding if the signed acknowledgement is not produced, the person relying on the lawfulness of the entry must prove the occupier gave consent to enter.

Division 3 Entry for checking compliance

116 Entry of place under s 111

Clause 116 applies to an entry made to check compliance with an order or notice and states the steps the authorised person must take prior to entry. The authorised person must make a reasonable attempt to locate the occupier of the place and obtain consent to enter, before entering the place. If entry is refused, the authorised person must obtain a warrant before entering the place.

If the authorised person is unable to locate an occupier after making a reasonable attempt to do so, entry may be made however a notice stating the date, time and purpose of entry must be left in a conspicuous position and in a reasonably secure way.

In determining reasonableness for the attempt of the occupier, the authorised person should give due regard to the definition of occupier, the amount of time taken to attempt to locate the occupier and other relevant criteria such as the size or location of the premises.

For reasonable security of a notice the authorised person should consider accessibility to the notice by persons other than the stated person on the notice and the likelihood that the notice could be otherwise misplaced or lost.

Division 4 Entry under warrant

Subdivision 1 Obtaining warrant

117 Application for warrant

Clause 117 allows an authorised person to apply to a magistrate for a warrant for a place and sets out the requirements of the application. The written application must state the grounds on which the warrant is sought and must be sworn. If all the information required by the magistrate about the application is not provided in the way the magistrate requires, the magistrate may refuse the application.

118 Issue of warrant

Clause 118 allows a magistrate to issue a warrant for a place only if the magistrate is satisfied there are grounds to believe there is a particular thing or activity at the place or will be at the place, within the next seven days that may provide evidence of an offence.

The clause lists what the warrant must state:

- the relevant place;
- that an authorised person may enter the relevant place and any other place necessary to allow entry into the relevant place and exercise their powers;
- the particulars of the offence;
- the name of the suspect person if known;
- the evidence that may be seized;
- the hours of entry;
- the magistrate's name;
- the day and time of the issue of the warrant; and

- the day the warrant ends (this must be within 14 days of the issue, unless the warrant allows for re-entry).

If the warrant is about a risk of medicinal cannabis being dispensed, supplied or issued to an unauthorised person or about the risk to a person's life, health or safety, the warrant may also state that the authorised person may enter the place again to check compliance with a disposal order issued as a result of the first entry into the place.

It the warrant allows for re-entry into the place, it expires seven days after the day given in the disposal order to destroy anything that was used, or is likely to be used, to commit an offence.

119 Electronic application

Clause 119 provides that an authorised person may make an application for a warrant under clause 117 electronically only if the authorised person considers there are urgent circumstances or other special circumstances, including a remote location.

The warrant cannot be made until the authorised person applies in writing, but can be made before the warrant is sworn.

120 Additional procedure if electronic application

Clause 120 provides a procedure in addition to clause 119 if an electronic warrant application is made. The magistrate can issue a warrant under this kind of application only if the magistrate is satisfied it was necessary to make the application electronically and it was made appropriately.

After issuing the warrant, if there is a way to get a copy of the warrant to the authorised person, the magistrate must do so. Otherwise, the magistrate must tell the authorised person:

- the relevant place;
- that an authorised person may enter the relevant place and any other place necessary to allow entry into the relevant place and exercise their powers;
- the particulars of the offence;
- the name of the suspect person if known;
- the evidence that may be seized;
- the hours of entry;
- the magistrate's name;
- the day and time of the issue of the warrant; and
- the day the warrant ends (this must be within 14 days of the issue, unless the warrant allows for re-entry).

The authorised person must write it all down on a form of warrant.

The copy of the warrant provided by the magistrate or the form of warrant written by the authorised person is as effectual as the original warrant.

As soon as possible the authorised person must send to the magistrate the written application for the warrant and the form of warrant, if completed. The magistrate must keep the original warrant and attach the written application for the warrant and the form of warrant given by the authorised person and give these to the clerk the court of the relevant magistrates court.

Despite the copy of the original warrant or the form of warrant being as effectual as the original warrant, if an issue arises in a proceeding about whether a power was exercised under the authority of the warrant and the original warrant is not produced as evidence, the onus of proof is on the person relying on the lawfulness of the exercise of the power to prove that the warrant authorised the exercise of the power.

121 Defect in relation to a warrant

Clause 121 provides that a warrant, including a copy of the original warrant or form of warrant applied for electronically, is not invalidated by a defect in the warrant or compliance with the proper process, unless the defect affects the substance of the warrant.

Subdivision 2 Entry procedure

122 Entry procedure

Clause 122 details the procedure for entry under a warrant. The authorised person must attempt to identify him or herself to an occupier who is present at the place, give the person a copy of the warrant, inform the person that the warrant permits entry to the place and give the person an opportunity to allow entry without using force. However, the authorised person does not need to comply with this procedure if immediate entry is required to effectively execute the warrant.

Part 3 Other authorised persons' powers and related matters

Division 1 Stopping or moving vehicles

123 Application of division

Clause 123 states that division 1 applies if an authorised person reasonably suspects or is aware that a thing in or on a vehicle provides evidence of the commission of an offence.

124 Power to stop or move

Clause 124 provides for an authorised person to direct a person in control of a moving vehicle to stop the vehicle and bring it to a convenient place to allow the authorised person to exercise his or her powers. The authorised person may also direct a person in control of a vehicle not to move the vehicle or to move the vehicle to a stated place in order for the authorised person to exercise their powers.

When giving a direction under this clause, the authorised person must give a warning that it is an offence not to comply with the direction.

125 Identification requirements if vehicle moving

Clause 125 details the actions the authorised person must take if they propose to give a direction to a person in control of a moving vehicle.

When the vehicle stops the authorised person must identify themself and produce his or her identity card for inspection by the person in control of the vehicle.

126 Failure to comply with direction

Clause 126 states that it is an offence (with a maximum penalty of 50 penalty units) to fail to comply with a direction given under clause 124 (Power to stop or move), unless the person has a reasonable excuse.

Reasonable excuses include, if the vehicle was moving and the authorised person did not identify themselves, or if to immediately comply would have endangered another person or caused loss or damage to property and the person complies as soon as practicable.

The offence does not apply to the situation where a direction is given to move or not to move a stationary vehicle and the person is not given the required offence warning.

Division 2 General powers of authorised persons after entering places

127 Application of division

Clause 127 states the powers under this division may be exercised if an authorised person enters a place. However, if the entry is subject to conditions, the powers under this division are to be exercised subject to any conditions.

128 General powers

Clause 128 states the general powers of an authorised person after entering a place. These include the powers to search, inspect, examine, film and to take things for examination. The powers also include the power to make an identifying mark or to reproduce documents or to use any person, equipment and materials reasonably required to enable the authorised person to exercise their powers. This may include making recordings or taking a person who has a specific expertise but is not an authorised person to assist with identifying relevant evidence.

If the authorised person takes a document or a device or article capable of producing a document (e.g. a computer or USB drive) from the place, the authorised person must copy or reproduce the document and return the original document or device to the place as soon as possible.

129 Power to require reasonable help

Clause 129 empowers the authorised person to require the occupier of the place or another person at the place to provide reasonable help to exercise a general power, such as producing a document or giving information. The authorised person must warn the person that it is an offence not to comply with a help requirement unless the person has a reasonable excuse.

130 Offence to contravene help requirement

Clause 130 provides for an offence (with a maximum penalty of 50 penalty units) for non-compliance with a help requirement unless the person has a reasonable excuse.

It is a reasonable excuse if complying with the requirement might incriminate the person or expose them to a penalty. It is not a reasonable excuse if a document or information is required to be held by the defendant under the Bill however, there is a limited immunity against the future use of the information or document given in compliance with the requirement.

Division 3 Seizure by authorised persons and forfeiture

Subdivision 1 Power to seize

131 Seizing evidence at a place that may be entered without consent or warrant

Clause 131 empowers an authorised person to seize evidence of an offence when entering a place that may be entered without consent and without a warrant.

132 Seizing evidence at a place that may be entered only with consent or warrant

Clause 132 details how an authorised person may seize evidence of an offence when entering a place that may be entered with consent or by warrant. Specifically, where a warrant has been issued, only evidence for the matter for with the warrant has been issued may be seized. However, if the authorised person finds other evidence of an offence being committed and they reasonably believe that failure to seize the evidence may result in the evidence being hidden, lost or destroyed, the seizure powers will apply.

133 Seizure of property subject to security

Clause 133 states that an authorised person may seize a thing despite a lien or other security for the thing being claimed by another person (e.g. a piece of manufacturing plant that is leased or hired from a third party is seized in evidence). However, the seizure does not affect the person's claim to the lien or security over the thing.

Subdivision 2 Powers to support seizure

134 Power to secure seized thing

Clause 134 provides for various ways in which a seized thing may be secured at the place of seizure, including sealing the thing, or the entrance to the place, by making a thing inoperable, or by requiring a person to do something to secure the seized thing. The thing may also be moved from the place of seizure.

135 Offence to contravene other seizure requirement

Clause 135 makes it an offence (with a maximum penalty of 100 penalty units) for a person who has been required to do something to a seized thing, not to comply with the requirement unless they have a reasonable excuse.

136 Offence to interfere

Clause 136 states that it is an offence (with a maximum penalty of 100 penalty units) to tamper with a seized thing unless approval has been given by the authorised person or there is a reasonable excuse.

It is also an offence (with a maximum penalty of 100 penalty units) to enter a place to which access has been restricted, or to tamper with anything used to restrict access, unless approval has been given by an authorised person or there is a reasonable excuse.

Subdivision 3 Safeguards for seized things

137 Receipt and information notice for seized thing

Clause 137 provides the process that an authorised person must follow after seizing a thing unless the thing doesn't belong to anyone or the condition, nature or value of it would not warrant compliance with this clause.

The authorised person must give the owner a receipt for the thing and an information notice explaining why the thing was seized. If the owner is not present, the receipt and notice must be left in a conspicuous and secure place.

This clause allows the authorised person to delay giving the receipt and notice if it is suspected that to do so would frustrate or hinder the investigation. Delay applies only to the extent that the authorised person remains at the place where the thing was seized. For example, an authorised person could not seize a thing, leave the place and return at a later time to provide the receipt and information notice.

The receipt and notice may be given in the same document and relate to more than one seized thing.

138 Access to seized thing

Clause 138 states that an authorised person must allow an owner of the seized thing to inspect the thing at any reasonable time. A reasonable time would be during normal business hours. If the seized thing is a document, the owner of the document must be allowed to copy it, free of charge. However, an inspection or copying of the document can be refused if to do so would be impracticable or unreasonable.

139 Return of seized thing

Clause 139 provides for a seized thing that is not forfeited or transferred to the State or which is not the subject of a disposal order. As soon as the chief executive determines that there is no reason to retain the thing it must be returned to its owner.

If a thing is not returned to the owner within 3 months of being seized, the owner may apply to the chief executive for its return. The chief executive must make a decision about the application within 30 days and either return the thing or retain it if there are reasonable grounds. The chief executive must give the owner a notice of the decision.

Subdivision 4 Forfeiture

140 Forfeiture by chief executive decision

Clause 140 states under what circumstances the chief executive may decide to forfeit a thing to the State, such as:

- the owner cannot be found after making reasonable inquiries
- the thing cannot be returned to the owner after making reasonable efforts, or
- to prevent the thing from being used to commit an offence.

To determine what is reasonable for inquiries and efforts regard can be had to the thing's condition, nature and value.

141 Information notice about forfeiture decision

Clause 141 states what must be done if the chief executive decides to forfeit a thing to the State. The chief executive must give the owner of the forfeited thing an information notice about the decision. The information notice must advise the owner of the thing that an application for a stay of the decision may be made if the owner wants to appeal the decision. The information notice may be given by leaving it at the place where the thing was seized, in a conspicuous position in a reasonably secure way.

The requirement to advise does not apply if forfeiture resulted from an inability to locate the owner or if an authorised person was unable to return the thing to the owner and the thing was seized at a public place or a place where the notice is unlikely to be read by the owner.

Subdivision 5 Dealing with property forfeited or transferred to State

142 When thing becomes property of the State

Clause 142 states how a thing becomes the property of the State. A thing becomes property of the State if it is forfeited to the State or the owner and the State agree to transfer the ownership of the thing to the State. The agreement must be in writing.

143 How property may be dealt with

Clause 143 describes how the chief executive may deal with seized property. The chief executive may deal with the thing as considered appropriate (e.g. sell it, destroying it or giving it away). The chief executive must not deal with the thing in a way that could prejudice the outcome of an appeal against the forfeiture. If the thing is sold, the proceeds of the sale may be returned to the former owner of the thing after deducting the costs of the sale. The clause is subject to any disposal order that may have been made by the court for the thing.

Division 4 Disposal orders

144 Disposal order

Clause 144 describes what the court may do if a person is convicted of an offence under the Bill. The court, on its own initiative or on an application by the prosecution, may make a disposal order for the disposal of anything owned by the person that was either the subject of, or used to commit the offence. A disposal order may also be made if the court considers it is likely that the thing could be used by the person or another person to commit a further offence.

In making this decision the court may require notice to be given to anyone the court considers appropriate, and must hear any submissions that any person claiming to have property in the thing may wish to make.

A disposal order may be made whether or not the thing has been seized under the Bill, and if it was seized, whether or not it has been returned to the owner. The court may also make any order to enforce the disposal order that it considers appropriate.

Division 5 Other information-obtaining powers of authorised persons

145 Power to require name and address

Clause 145 provides for an authorised person to, under certain circumstances, require a person to give their name and address. The circumstances for which this requirement may be made are when:

- the authorised person finds a person committing an offence against the Bill; or
- when there is reasonable suspicion that a person has just committed an offence against the Bill; or
- when there is information that leads the authorised person to suspect that an offence against the Bill has just been committed.

The authorised person may also require evidence be produced that verifies the correctness of the information provided by the person if it is reasonable to expect that the person should be in possession of such evidence.

An offence warning for the requirement must be given to the person to advise that it is an offence not to comply with the requirement.

146 Offence to contravene personal details requirement

Clause 146 states that it is an offence (with a maximum penalty of 50 penalty units) for a person not to comply with a personal details requirement made under clause 145 unless the person has a reasonable excuse. However, the person can only be convicted of this if they are found guilty of the offence for which the personal details requirement was made.

147 Power to require production of document

Clause 147 provides for an authorised person to make a document production requirement that requires a person to make available for inspection the following:

- a document issued to the person under the Bill (e.g. a medicinal cannabis approval);
- a document required to be kept by the person under the Bill (e.g. a medicinal cannabis management plan); or
- a clear reproduction of a document or information required to be kept under the Bill which is stored or recorded by means of a device (e.g. an electronic prescription).

The authorised person may copy the document and require the person responsible for keeping the document to certify that the copy is a true copy of the document. The copy may be for the whole document or an entry in the document. The requirement is referred to as a document certification requirement.

The authorised person must return the document to the person as soon as the document has been copied unless the person has not complied with a document certification requirement.

148 Offence to contravene document production requirement

Clause 148 states that it is an offence (with a maximum penalty of 50 penalty units) to not comply with a document production requirement unless the person has a reasonable excuse. However, it is not a reasonable excuse to not comply on the basis that to comply might tend to incriminate the person or expose the person to a penalty.

The authorised person must advise the person that they must comply with the requirement even though complying might tend to incriminate the person or expose the person to a penalty but there is a limited immunity against the future use of the information or document given in compliance with the requirement. In order for a person to be able to be convicted of the offence, the authorised person must give this advice.

If a court convicts a person for non-compliance of this clause, as well as imposing a penalty, the court may also order the person to comply with the document production requirement.

149 Offence to contravene document certification requirement

Clause 149 states that it is an offence (with a maximum penalty of 50 penalty units) to not comply with a document certification requirement unless the person has a reasonable excuse. However it is not a reasonable excuse to fail to comply if it might tend to incriminate the person or expose the person to a penalty.

The authorised person must advise the person that they must comply with the requirement even though complying might tend to incriminate the person or expose the person to a penalty but there is a limited immunity against the future use of the information or document given in compliance with the requirement. In order for a person to be able to be convicted of the offence, the authorised person must give this advice.

If a court convicts a person for non-compliance of this clause, the court may also order compliance with the document certification requirement.

150 Power to require information

Clause 150 provides for an authorised person to give a notice to a person to give information related to the offence at a stated time and place. The requirement may be made if the authorised person reasonably believes that an offence against the Bill has been committed and a person may be able to provide information about the offence.

The requirement is an information requirement. If the information required is an electronic document, the person must provide a clear image or written version of the electronic document.

151 Offence to contravene information requirement

Clause 151 states that it is an offence (with a maximum penalty of 50 penalty units) to not comply with an information requirement unless the person has a reasonable excuse. It is a reasonable excuse not to comply with the requirement if giving the information might tend to incriminate or expose the person to a penalty.

Division 6 Power to remove or reduce diversion risk or substance risk

152 Power to remove or reduce risk stated in warrant

Clause 152 provides an authorised person with the ability to take the steps necessary to remove or reduce a diversion risk or a substance risk for medicinal cannabis at a place where entry has been made under a warrant and the warrant authorises the authorised person to exercise powers under this division.

Part 4 Analysis of things

153 Chief executive may approve laboratory

Clause 153 states the chief executive may approve a laboratory to analyse things taken under the Bill if the laboratory has the resources and expertise to conduct the analysis.

154 Analysis

Clause 154 states that an authorised person must give, as soon as practicable, a thing taken for analysis to a State analyst. The State analyst must then analyse the thing or give the thing to an approved laboratory for analysis.

If the State analyst undertakes the analysis, the analyst must, as soon as practicable, prepare a certificate of analysis and give the certificate to the authorised person who took the thing.

If an approved laboratory undertakes the analysis, the State analyst must, as soon as practicable, obtain a certificate of analysis from the laboratory and give the certificate to the authorised person who took the thing.

155 Certificate must indicate methodology used

Clause 155 states that the certificate of analysis must include information about the method of analysis used. There may be more than one accepted method of analysis and different methods may elicit more or less accurate results. The method of analysis may be used in a court proceeding about the thing.

Part 5 Miscellaneous provisions relating to authorised persons

Division 1 Damage

156 Duty to avoid inconvenience and minimise damage

Clause 156 states that an authorised person must, in the exercise of a power, take reasonable care to cause as little inconvenience and damage as possible.

157 Notice of damage

Clause 157 states the actions an authorised person must take if the authorised person or a person acting under their direction, causes damage in the course of exercising a power. The authorised person must give a notice of the damage to a person who, in the opinion of the authorised person, is in control of, or is the owner of the damaged thing. If it is not practical to give the notice to the person, the authorised person must leave the notice in a secure and conspicuous position at the place where the damage happened.

If the authorised person reasonably believes that to comply with requirement to give the notice may frustrate or hinder the performance of the authorised person's function, the giving of the notice may be delayed. Here delay applies only to the extent that the authorised person continues to have a reasonable suspicion and remains in the vicinity of the place where the thing was damaged.

If the damage is believed to have been caused by a defect in the thing or by other circumstances beyond the control of the authorised person or person under their direction, the belief must be stated in the notice.

The notice must state the particulars of the damage and that the person who suffered the damage may claim compensation. Provisions relating to compensation are detailed in clause 190.

Division 2 Compensation

158 Compensation

Clause 158 provides for a person who incurs loss because of the exercise of powers of an authorised person, to claim compensation from the State. The loss may include a loss arising from compliance with a requirement made under the seizure, forfeiture or disposal order provisions of Part 3.

Compensation may be claimed and ordered in a proceeding brought in a court with jurisdiction for the recovery of the amount claimed, or in a proceeding for an alleged offence against the Bill where the investigation of the offence gave rise to the claim.

If the court is satisfied that the claim is justified under the circumstances, the court may order the payment of compensation. In determining whether compensation should be ordered the court must consider any relevant offence committed by the claimant and whether the actions that resulted in the loss where as the result of lawful seizure or forfeiture.

Additional matters that may be taken into account by the court with respect to compensation claims may be prescribed by regulation.

Division 3 Other offences relating to authorised persons

159 Giving authorised person false or misleading information

Clause 159 states that it is an offence (with a maximum penalty of 50 penalty units) to give an authorised person false or misleading information in relation to the administration of the Bill. However, an offence does not occur if the person gives the information in a document and tells the authorised person how the document is false or misleading and the person can provide the correct information.

160 Obstructing authorised person

Clause 160 states that it is an offence (with a maximum penalty of 100 penalty units) to obstruct an authorised person exercising a power unless the person has a reasonable excuse. It is also an offence to obstruct a person who is assisting an authorised person to exercise a power.

The authorised person must warn the person who has obstructed the authorised person (or assistant) that it is an offence to cause an obstruction unless there is a reasonable excuse.

A definition of *obstruct* is provided and includes assault, hinder, resist, attempting to obstruct and threatening to obstruct.

161 Impersonating authorised person

Clause 161 states that it is an offence (with a maximum penalty of 100 penalty units) to impersonate an authorised officer.

Division 4 Other provisions

162 Evidential immunity for individuals complying with particular requirements

Clause 162 provides for immunity of certain officials. The person is not liable to any penalty in respect of anything done by the person under the Bill or regulations.

Clause 162 states that where a person provides information or a document, the evidence derived is not admissible against the individual or will not expose the individual to a penalty in a proceeding.

This provision does not apply to a proceeding about the false or misleading nature of the information or document, which is relevant evidence for the proceeding.

Part 6 Recall orders and public warnings

Division 1 Recall orders

163 Chief executive may make recall order

Clause 163 states that recall orders may be issued by the chief executive in order to prevent or minimise risk or harm to a person's life, health or safety because of the use of a form or type of medicinal cannabis.

The chief executive may issue a recall order to a person who is authorised to dispense, manufacture or give a direction for medicinal cannabis that requires the person to recall from use or distribution a product that is, or contains medicinal cannabis.

The chief executive may make the recall order if the chief executive reasonably considers there is a risk of harm to persons that are, or could foreseeably be, exposed to the product. Instances of when an order would be necessary to prevent or minimise such harm include the following:

- the product labelling or instruction for use is inaccurate, or the product packaging is not sufficiently secure
- the product, when used according to the instruction for its use, is not safe or effective.

It is an offence carrying a penalty of a maximum 500 penalty units not to comply with a recall order (see clause 97).

164 Notice required for making recall order

Clause 164 states that before making a recall order the chief executive must do the following:

- give the person who is authorised to dispense, manufacture or give a direction for medicinal cannabis notice of the intention to make the order, and the reasons for making the order;
- give the person a copy of the proposed order; and
- invite them to show cause why the order should not be made.

This notice need not be given if the chief executive reasonably considers the recall order must be made immediately to prevent significant and imminent harm to a person. However, as soon as practicable (and no later than 48 hours after the order is made) the chief executive must do the following:

- give a copy of the order to the person;
- give the person a written notice of the reasons for making the order; and
- invite the person to show cause why the order should be revoked.

The person may make written submissions within seven days after receiving a notice, and the chief executive must consider these before making any decision to make or revoke the recall order.

165 Decision about recall order

Clause 165 states that if the chief executive decides to make a recall order, or to not revoke a recall order, he must give the person a written copy of the recall order and an information notice for the decision.

166 Notifying public about recall order

Clause 166 states that information to alert the public about the potential harm identified in the recall order, must be published on the department's website.

167 Content of recall order

Clause 167 details what must be stated on the recall order. The recall order must state the reasons for recalling the stated product, what the person must do to recall the product, and the period for which the order is in effect. The action which the person is required to do may include the following:

- stop the manufacture or supply of the product;
- take reasonable steps to recover the product from another person;
- isolate or destroy the product;
- repackage or relabel the product; and
- publish warnings about the product.

168 Nature of recall order

Clause 168 states that the person to whom the recall order is issued, is liable for any cost incurred in relation to complying with the recall order. The recall order remains in force for the period stated in the order, unless it is revoked by the chief executive.

Division 2 Public warnings

169 Statement of warning

Clause 169 provides for the Minister or chief executive to make or issue a public statement identifying and giving warnings or information. Such statements may identify and be about the following:

- contraventions of the Bill that resulted in notification action being taken (being a recall order, compliance notice or show cause notice), and the persons who committed the contraventions;
- practices regulated under a relevant law;
- that, in the reasonable opinion of the Minister or chief executive, are unlawful; or
- the commission of offences against a relevant law and the persons who commit the offences.

However, the Minister or chief executive must not make or issue a statement unless satisfied it is in the public interest to do so, and a public statement or warning has not been released (or is not about to be released) under another process that is more appropriate to the circumstances. It is in the public interest if the Minister or chief executive considers the statement necessary to prevent or minimise the risk of harm to a person's life, health or safety.

Chapter 8 Expert advisory panel

Part 1 Establishment

170 Establishment

Clause 170 provides for the chief executive to establish an expert advisory panel.

171 Role

Clause 171 sets out the role of the expert advisory panel.

The panel is to have an advisory role in that it will, at the request of the chief executive, provide advice and make recommendations about applications for medicinal cannabis approvals, dispensing approvals or clinical trial approvals.

The panel will also have a monitoring role by monitoring the use of medicinal cannabis in Queensland, research related to the therapeutic use of cannabis products and advancements and development in the field.

172 Membership

Clause 172 allows the chief executive to appoint the members of the expert advisory panel on a temporary or permanent basis. The chief executive may revise the membership of the panel by adding or removing members from time to time.

When appointing members, the chief executive will have regard to a person's experience and expertise in areas relating to the manufacture and use of medicinal cannabis. For example, science and medicine, justice and law, ethics, culture or sociology or agriculture.

173 Remuneration and appointment conditions of members

Clause 173 provides that the chief executive may decide to pay a member of the expert advisory panel remuneration or allowances and may decide the terms and conditions of a member's office that are not provided for under this Bill.

174 Resignation and removal of members

Clause 174 provides that a member may resign from the expert advisory panel by giving a signed notice to the chief executive or the chief executive may remove a member from the panel for any reason or for no reason.

175 Chairperson

Clause 175 provides for the appointment of a chairperson. The chief executive must appoint one member of the expert advisory panel to be the chairperson for the term the chief executive decides. The office of the chairperson becomes vacant if the person resigns from the office by signed notice given to the chief executive or is no longer a member of the panel. However, a person can resign from the office of the chairperson but continue to be a member of the panel.

176 Deputy chairperson

Clause 176 provides for the appointment of a deputy chairperson. The chief executive must appoint one member of the expert advisory panel to be the deputy chairperson for the term the chief executive decides. The office of the deputy chairperson becomes vacant if the person resigns from the office by signed notice given to the chief executive or is no longer a member of the panel. However, a person can resign from the office of the chairperson but continue to be a member of the panel. The deputy chairperson may act as the chairperson if the chairperson is absent or the office is vacant.

Part 2 Operations

177 Conduct of operations and proceedings

Clause 177 gives the expert advisory panel the power to conduct its operations and proceedings, including its meetings as it considers appropriate.

178 Working groups

Clause 178 allows the chairperson, with the agreement of the chief executive, to establish one or more working groups to assist the expert advisory panel as needed. The chairperson is to decide on the membership and functions of a working group.

Chapter 9 Review and appeals

Part 1 Interpretation

179 Definitions for chapter

Clause 179 provides definitions for this part of the Bill.

Internal review application means an application to the chief executive made by someone who has been given an information notice for an original decision to review the decision.

Internal review decision means the decision made by the chief executive after conducting a review of an original decision for an internal review application. The decision may be to confirm the original decision, amend the original decision or substitute the decision.

Original decision means any decision made under this Bill except for certain conditions placed on approvals.

Part 2 Internal reviews

180 External review or appeal process starts with internal review

Clause 180 states that a person may not apply to the Queensland Civil Administrative Tribunal (QCAT) for review of an original decision (being a decision made under the Bill), or appeal against an original decision to a court, unless the person has first applied for an internal review.

181 Who may apply for internal review

Clause 181 states that a person who is given an information notice for an original decision may apply to the chief executive for an internal review of the decision.

A person who is entitled to be given an information notice (but has not yet received one) may ask the chief executive for a notice for the decision. If no such notice is given, the person may still apply for a review of the decision.

182 Internal review application

Clause 182 states that an internal review application must be in the approved form, and supported by enough information to enable the chief executive to decide the application. The application must be made within 14 days after the applicant is given the information notice, however, the chief executive may (at any time) extend the time for making the internal review application.

183 Stay of operation of original decision

Clause 183 states an internal review application does not stay the original decision. However, the applicant may immediately apply to the relevant reviewing body (being the court for an original decision to seize or forfeit a thing, or QCAT for another original decision) for a stay of the original decision. An internal review application only affects the original decision (or carrying out of the decision) if the decision is stayed.

To ensure the effectiveness of any later review (and appeal), the reviewing body may stay the original decision. The stay may be given on conditions the reviewing body considers appropriate, and may be amended or revoked by the reviewing body. The stay operates for the period fixed by the reviewing body, however this period must not extend past the time when the chief executive makes an internal review decision and any later period the reviewing body allows for an appeal.

184 Internal review

Clause 184 states that within 28 days after receiving an internal review application, the chief executive must conduct an internal review of the original decision, and make the internal review decision to confirm the original decision, amend this decision or substitute another decision.

The application must be dealt with by a person who did not make the original decision and by a person in a more senior office than the person who made the original decision (although this does not apply to an original decision made by the chief executive personally). Section 27A of the *Acts Interpretation Act 1954* does not alter this provision.

For the purpose of an appeal or external review, if the internal review decision confirms the original decision, the original decision is taken to be the internal review decision. However, if the internal review decision amends the original decision, the original decision as amended is taken to be the internal review decision.

185 Notice of internal review decision

Clause 185 states that within 14 days after making an internal review decision, the chief executive must give notice of the decision to the applicant. If the decision is not the one sought by the applicant, the notice must include the following:

- for the review of an original decision to seize or forfeit a thing, state the day the notice is given to the applicant, the reason for the decision, that the applicant may appeal against the decision to a court (within 28 days after the notice is given), how to make this appeal, and that the applicant may apply to the court for a stay of the internal review decision; or
- for the review of another original decision, be accompanied by an information notice for the internal review decision.

If the chief executive does not give the notice within the 14 days, the chief executive is taken to have made an internal review decision confirming the original decision.

Part 3 External reviews by QCAT

186 Who may apply for external review

Clause 186 states a person may to apply to QCAT for an external review of an internal review decision. A person may apply to QCAT (in the manner prescribed in the QCAT Act) if they have been given (or are entitled to be given) an information notice for an internal review decision.

Part 4 Appeals

187 Who may appeal

Clause 187 states a person may appeal to the court in relation to an internal review decision. A person may apply to the court if the original decision was to seize or forfeit a thing, and they are dissatisfied with the internal review decision of that original decision.

188 Procedure for an appeal to court

Clause 188 states that an appeal is started by filing a notice of appeal with the clerk of the court. The notice of appeal must be filed within 28 days after the appellant receives notice of the internal review decision, however the court may extend the time for filing this notice.

The notice of appeal must state fully the grounds of the appeal. A copy of the notice must be served on the chief executive.

189 Stay of operation of internal review decision

Clause 189 states that to ensure the effectiveness of the appeal, the court may grant a stay of the operation of an internal review decision. An appeal only affects the internal review decision (or carrying out of the decision) if the decision is stayed.

The stay may be given on conditions the court considers appropriate, and may be amended or revoked by the court. The stay operates for the period fixed by the court, however this period must not extend past the time when the court decides the appeal.

190 Powers of court on appeal

Clause 190 states that in deciding an appeal, the court has the same powers as the chief executive when making the internal review decision.

An appeal is by way of rehearing, and while not bound by the rules of evidence, the court must comply with natural justice.

The court may confirm the internal review decision, or set aside the decision and substitute another decision, or set aside the internal review decision and return the matter to the chief executive with directions the court considers appropriate.

191 Effect of decision of court on appeal

Clause 191 states that if the court sets aside the internal review decision and returns the matter to the chief executive with directions, and the chief executive makes a new decision in accordance with the directions, the new decision is not subject to any further review or appeal.

If the court substitutes another decision for the internal review decision, the substituted decision is taken to be the decision of the chief executive, and the chief executive may give effect to the substituted decision as if it were his or her original decision. No application for review or appeal had been made.

Chapter 10 Protection from liability

192 Definitions for chapter

Clause 192 defines the terms ***civil claim*** and ***civil liability***.

193 Protection from liability in relation to monitoring and enforcement

Clause 193 provides protection for prescribed persons when performing their roles and functions, in good faith and without negligence under the Bill to monitor, investigate or enforce compliance in relation to medicinal cannabis. These persons could be, and include the chief executive, an authorised person or State analyst, or an officer of the department or a person acting under the direction of any of these.

If a liability were to attach to one of these persons, the liability will instead attach to the State.

194 Protection from liability in relation to medicinal cannabis

Clause 194 provides a specific protection for persons acting in good faith and without negligence from liability in relation to medicinal cannabis.

The persons covered by this protection are:

- a member of the expert advisory panel;
- a single-patient prescriber;
- a patient-class prescriber; or
- an approved pharmacist or secondary dispenser.

The actions that are covered by this protection are:

- an application for the grant, amendment or replacement of a medicinal cannabis approval;
- the grant, amendment or replacement of a medicinal cannabis approval;
- administrative action about a medicinal cannabis approval;
- the giving of a lawful direction for a medicinal cannabis approval;
- the dispensing of medicinal cannabis; and
- any result of the taking of the above actions.

This clause makes it clear that it does not apply to the chief executive or officer of the department as they are protected from civil liability under the *Public Service Act 2008.*

195 Protection from liability in relation to reviews

Clause 195 provides a further protection in relation to reviews of decisions. The clause prevents a liability attaching to a person who is in good faith and without negligence applying for, or otherwise being involved in a review of a decision, or giving advice or information to the chief executive, or acting under direction of the chief executive for the review.

This clause makes it clear that it does not apply to the chief executive or officer of the department as they are protected from civil liability under the *Public Service Act 2008.*

196 Civil remedies not otherwise affected

Clause 196 clarifies that apart from the protections set out in this chapter, nothing in the Bill affects or limits

Chapter 11 Legal proceedings

Part 1 Evidence

197 Application of part

Clause 197 states that the division applies to legal proceedings under the Bill.

198 Appointments and approvals

Clause 198 states that in proceedings, the appointment of the chief executive, an authorised person or State analyst and a member of the expert advisory panel and the authority of those persons to do anything in relation to legal proceedings, must be presumed (unless a party, by reasonable notice, requires proof of those matters).

199 Signatures

Clause 199 states that a signature purporting to be the signature of the chief executive, an authorised person or State analyst or a member of the expert advisory panel is evidence of the signature it purports to be.

200 Evidentiary aids

Clause 200 states the matters that may be used as evidentiary aids in a matter. In a complaint starting a proceeding, a statement that the matter came to the knowledge of the complainant on a stated day is evidence of when the matter came to the complainant's knowledge.

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

- a stated document is (a) an appointment or decision, (b) an approval, (c) notice, direction or requirement, (d) code, guideline, protocol or standard, (e) another document given to the chief executive or otherwise kept under the Bill, or (f) a copy of, or an extract from a part of, one of those things;
- on a stated day, or during a stated period, a stated person was or was not the holder of an approval;
- on a stated day, or during a stated period, an approval was or was not in force, or was or was not subject to a stated condition;
- on a stated day, an approval was suspended for a stated period, surrendered or cancelled;
- on a stated day, or during a stated period, an appointment as an authorised person or State analyst was or member of the expert advisory panel, or was not, in force for a stated person;
- on a stated day (a) a stated person was given a stated notice or direction, (b) a stated requirement was made of a stated person, or (c) a stated amount is payable by a stated person.

For the start of a proceeding, a statement that a matter came to the complainant's knowledge on a stated day is evidence of when the matter came to the complainant's knowledge.

In relation to a thing seized or taken by an authorised person, a certificate purporting to be that of a state analyst stating any of the following matters is evidence of the matter:

- the analyst's qualifications;
- the analyst took or received the thing from a stated person, and it was analysed at a stated place on a stated day or during a stated period; and
- the methodology used to analyse the thing and the results of the analysis.

In a proceeding in which the chief executive applies to recover costs (clause 205), a certificate by the chief executive stating that stated costs were incurred and the way in which, and purpose for which, they were incurred is evidence of the matters stated.

201 Evidence of medicinal cannabis

Clause 201 states in a legal proceeding in which a particular substance must be proved to be a medicinal cannabis, evidence that a substance is commonly supplied under the same name or description as the particular substance, and is a type of medicinal cannabis, will be evidence that the particular substance is also that type or form of scheduled substance.

Further, evidence that the substance, or container for the substance is labelled, marked or inscribed as required for that type or form of medicinal cannabis, is evidence that the substance is the type or form of medicinal cannabis as labelled, marked or inscribed.

Part 2 Proceedings

202 Offences against this Act

Clause 202 states that an offence against the Bill is a summary offence.

A proceeding for the offence must start within one year after the offence was allegedly committed, or six months after the offence comes to the complainant's knowledge (but within 2 years after the offence was allegedly committed), whichever period is the later.

203 Proceeding not to commence if compliance notice in effect

Clause 203 applies to a person who has been given a compliance notice stating a provision that it is an offence to contravene. The person cannot be prosecuted for the offence unless they fail to comply with the notice and do not have a reasonable excuse for failing to comply.

204 Allegations of false or misleading information or document

Clause 204 states that in a proceeding for an offence involving false or misleading information, or a false or misleading document, it is sufficient for a charge to state that the information or document was 'false or misleading' to the person's knowledge, without specifying which.

205 Recovery of costs of investigation

Clause 205 states that if the following conditions apply, a court may order a person to pay the chief executive an amount equal to costs incurred by the chief executive if all the following apply:

- a court convicts a person of an offence against the Bill;
- the chief executive applies to the court for an order against the person for the payment of the costs the chief executive incurred in taking a thing, conducting an analysis or doing something else for the investigation of the offence; and
- the court finds the chief executive has reasonably incurred the costs, and is satisfied it would be just to make the order in the circumstances of the particular case.

An application to a court for costs, and an order made by the court on the application, is a judgment in the court's civil jurisdiction. As such, an issue arising in the application must be decided on the balance of probabilities.

This power to award costs does not limit the court's powers under the *Penalties and Sentences Act 1992* or another law.

206 Responsibility for acts or omissions of representatives

Clause 206 states that in proceedings for offences where a person's state of mind is relevant, their state of mind may be determined by reference to the person's representative. For a corporation, a representative means its executive officer, employee or agent, and for an individual, a representative means their employee or agent. An executive officer of a

corporation is a person who is concerned with, or takes part in, the corporation's management, whether or not they are a director or their position is called 'executive officer'.

Where it is relevant to prove a person's state of mind about a particular act or omission, it is sufficient to show the act was done or omitted to be done by a representative of the person within the scope of the representative's actual or apparent authority, and the representative had the necessary state of mind.

A person's state of mind includes their knowledge, intention, opinion, belief or purpose, and the person's reasons for this intention, opinion, belief or purpose.

An act done or omitted to be done for a person by their representative within the scope of the representative's actual or apparent authority is taken to also have been done or omitted to be done by the person, unless the person proves they could not, by the exercise of reasonable diligence, have prevented the act or omission.

207 Executive officer may be taken to have committed offence

Clause 207 states that if a corporation commits a serious offence (clauses 92 to 97), each executive officer of the corporation is taken to have also committed the offence if they authorised or permitted the corporation's conduct constituting the offence, or they were knowingly concerned, either directly or indirectly, in the corporation's conduct.

Proceedings may be conducted against the executive officer, and they may be convicted of the offence, whether or not the corporation has also been proceeded against or convicted in relation to that offence. However, this does not affect the liability of the corporation for the offence, or the liability of any person (under chapter 2 of the Criminal Code), whether or not the person is an executive officer of the corporation, for the offence.

Chapter 12 General

Part 1 Confidentiality

208 Definitions for part

Clause 208 defines the meaning of certain words that are used in part 1:

- *administrator* means a person who is, or was, the chief executive or a person who is or was involved in the administration or involvement of this Bill.
- *confidential information* means information that is not publicly available, such as a person's personal affairs or health, which the administrator has obtained while performing their functions under this Bill.

209 Confidentiality of information

Clause 209 states that it is an offence (with a maximum penalty of 50 penalty units) for an administrator, either directly or indirectly, to disclose confidential information.

However, it is not an offence if the confidential information is disclosed:

- under this Bill;
- with the written consent of the person to whom the information relates;

- to the person whom the information relates; or
- in a way that could not identify any person.

The clause notes that the *Hospital and Health Boards Act 2011*, section 142 does not apply in relation to administrators and confidential information under this Bill.

210 Disclosure of information to entities performing relevant functions

Clause 210 states an administrator can only disclose the confidential information to the below entities if they are satisfied that the information will be collected, stored and used by the entity in a way that protects to the extent possible, the identity of the person the subject of the information and that the disclosure is necessary for the entity to exercise its functions:

- a coroner investigating the death of a person;
- the health ombudsman conducting an investigation;
- a law enforcement agency detecting, preventing, investing or prosecuting an offence involving medicinal cannabis;
- the Australian Pesticides and Veterinary Medicines Authority performing its functions under the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth) or the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth);
- The Therapeutic Goods Administration performing its functions under the *Therapeutic Goods Act 1989* (Cwlth); or
- Another Commonwealth or State entity performing its functions relating to services provided by or the regulation of health practitioners, the administration of another jurisdiction's law dealing with medicinal cannabis or the administration of the *Food Act 2006*, the *Food Production (Safety) Act 2000* (or another jurisdiction's law dealing with food and food safety).

211 Disclosure for care or treatment of person

Clause 211 states that an administrator may disclose confidential information to a health practitioner who is providing care or treatment to the person to whom the information relates.

212 Disclosure for medicinal cannabis approval

Clause 212 is a specific disclosure provision relating to a medicinal cannabis approval. A person who is a single-patient prescriber for the approval may disclose to the chief executive information about the patient for the approval. A person who is applying for the approval may disclose information to the chief executive about the patient named on the application for the approval.

213 Disclosure to protect public health or safety

Clause 213 states that the chief executive may give the Commonwealth or State entity the confidential information that is necessary for the Commonwealth or State entity to act in relation to a risk that medicinal cannabis being dispensed, supplied or issued to a person not authorised or a risk of harm to the life, health or safety of a person. This clause only applies if the chief executive believes a substance risk exists because of a person's actions.

214 Requests by chief executive for information

Clause 214 states that the chief executive may, by a notice, ask a public entity, such as a public sector unit, to give information to the chief executive to assist in the performance of his or her functions and to prevent an imminent risk that medicinal cannabis being dispensed,

supplied or issued to a person not authorised or a risk of harm to the life, health or safety of a person.

The public entity must comply with the notice unless they consider that the disclosure of the information would prejudice the investigation, or possible contravention, of a law; would prejudice the effectiveness of a lawful method or procedure for preventing, detecting, investigating or dealing with a contravention or possible contravention of a law; or would endanger a person's life or physical safety.

When complying with the notice, the public entity and chief executive must ensure the information only relates to the chief executive's function under this Bill and that the privacy of the person to whom the information relates is protected.

Part 2 Miscellaneous

215 Delegation by chief executive

Clause 215 allows the chief executive officer to delegate his or her functions and powers under this Bill to an appropriately qualified public service officer or employee or health service employee.

216 Approved forms

Clause 216 allows the chief executive to approve forms, including electronic forms, for use under this Bill.

217 Regulation-making power

Clause 217 provides the head of power for the making of a regulation which may be required for the operation of the Bill. The clause provides that regulations made be made by Governor in Council for all aspects relating to the provision of medicinal cannabis. The clause also provides the head of power for the regulation to impose a penalty of not more than 100 penalty units for a contravention of the regulation.

Chapter 13 Transitional provision

218 Existing approval for medicinal cannabis

Clause 218 provides for the transition of any existing approvals given under section 270B of the *Health (Drugs and Poisons) Regulation 1996*. Under section 270B of that regulation, the chief executive has the power to grant an approval to administer, dispense, supply or use cannabis for or connected with an approved clinical trial or for an approval previously given under the Commonwealth's *Therapeutic Goods Act 1989*.

An existing approval for a clinical trial is taken to be a clinical trial approval under this Bill and an approval previously given under the Commonwealth's *Therapeutic Goods Act 1989* is taken to be a medicinal cannabis approval under this Bill until:

- An equivalent approval is granted to replace the existing approval;
- the term of the existing approval ends; or
- the existing approval is cancel or surrendered.

However, if a person applies for a new approval before the existing approval's term ends and the chief executive has not yet decided the application, the approval for a clinical trial is taken to be a clinical trial approval under this Bill and an approval previously given under the Commonwealth's *Therapeutic Goods Act 1989* is taken to be a medicinal cannabis approval under this Bill until the chief executive makes a decision.

No approvals under the *Health (Drugs and Poisons) Regulation 1996*, section 270B have been given for clinical trials yet and one approval has been given to approval to administer, dispense, supply or use cannabis for or connected with an approved clinical trial or for an approval previously given under the Commonwealth's *Therapeutic Goods Act 1989.*

Chapter 14 Consequential amendments

Part 1 Amendment of this Act

219 Act amended

Clause 219 states that this part amends the *Health Act 1937.*

220 Amendment of long title

Clause 220 amends the long title of the *Health Act 1937.*

Part 2 Amendment of *Health Act 1937*

221 Act amended

Clause 221 amends the *Public Health (Medicinal Cannabis) Act 2016.*

222 Amendment of section 5 (Interpretation)

Clause 222 amends the *Public Health (Medicinal Cannabis) Act 2016* to update the long title once the amendment to the *Health Act 1937* takes effect.

Part 3 Amendment of *Health (Drugs and Poisons) Regulation 1996*

223 Regulation amended

Clause 223 provides for the amendment of the *Health (Drugs and Poisons) Regulation 1996.*

224 Omission of s 77 (Approved drug —dronabinol (*delta*-9-tetrahydrocannabinol))

Clause 224 omits section 77.

225 Amendment of section 270A (Approval must not be granted for therapeutic use of S9 poisons)

Clause 225 omits reference to section 270B as a consequential amendment to the omission of section 270B by clause 226.

226 Omission of section 270B (Approval for cannabis)

Clause 226 provides for the omission of section 270B as the approvals covered by that section are now included in this Bill.

Schedule 1 Dictionary

Schedule 1 defines certain words and terms used throughout the Bill, some of which are duplicated in these explanatory notes to assist the interpretation of particular clauses.