

## **REPLACEMENT EXPLANATORY STATEMENT**

### *Narcotic Drugs (Licence Charges) Act 2016*

### *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021*

The Regulations make minor amendments for consistency with the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* with the ultimate proposed effect of reduction in regulatory burden for applicants for, and holders of, licences and permits for medicinal cannabis, improving the availability of product for supply for the treatment of patients with conditions for which medicinal cannabis is indicated.

The *Narcotic Drugs (Licence Charges) Act 2016* (the Charges Act) imposes annual charges on licences granted under the *Narcotic Drugs Act 1967* which relate to cannabis. The Office of Drug Control (ODC), which is part of the Department of Health (the Department), is responsible for administering the Act.

Section 9 of the Charges Act provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed. Subsection 6(1) of the Charges Act provides that charge is imposed on a licence that, relevantly, is in force at any time during such period as is prescribed by the regulations. Subsection 8(1) of the Charges Act provides that the amount of the charge for a period is such amount as is prescribed by the regulations.

The *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021* (the Regulations) make minor amendments for consistency with the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act), which amends the *Narcotic Drugs Act 1967* (the Narcotic Drugs Act) for various purposes including to introduce a single licence model for medicinal cannabis regulation. The Amendment Act will commence six months from its passage, being on 24 December 2021, and finalises implementation of recommendations of the final report of the McMillan Review by Professor John McMillan AO requiring legislative change. This statutorily required review of the medicinal cannabis scheme in the Narcotic Drugs Act was completed by tabling of the final report in the Parliament on 5 September 2019.

Specifically, the Regulations, using key terminology to be introduced by the cognate *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, provide for charge for new single licences (and associated permits) to be transitioned by the Amendment Act from the existing licence framework. The proposed Regulations also provide for certain transitional arrangements until the end of the financial year.

During 2019–20, the Department consulted industry stakeholders on the detailed policy measures required to implement the recommendations of the McMillan Review through publication of consultation papers and conducting a number of forums held in Brisbane, Sydney and Melbourne. On 17 November 2020, the Department conducted a further industry

information session on the proposed measures. During 2021, the Department has continued its consultation with industry by hosting a number of webinars.

The Department also proposes to undertake a review (including with public consultation) of the amounts and application for charge for the medicinal cannabis scheme in early 2022, in accordance with activities based costing principles and the Australian Government Charging Framework, with any changes to take effect in the 2022-23 financial year

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence after the proposed Regulations are registered, and immediately after the commencement of the Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021.

Details of the Regulations are set out in the [Attachment](#).

Authority: Section 9 of the *Narcotic Drugs (Licence Charges) Act 2016*

**Details of the *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021***

**Section 1 – Name**

This section provides that the title of the Regulations is the *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021*.

**Section 2 – Commencement**

Subsection 2(1) provides for the Regulations to commence on the later of immediately after the commencement of the *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021* (the Medicinal Cannabis Amendment Regulations) and the day after registration of the Regulations on the Federal Register of Legislation, but will not commence at all if the Medicinal Cannabis Amendment Regulations do not commence. Subsection 2(2) provides that any information in column 3 of the table in subsection (1) is not part of the instrument. It notes that information may be inserted in column 3, or information in it may be edited, in any published version of this instrument.

**Section 3 – Authority**

The Regulations are made under the *Narcotic Drugs (Licence Charges) Act 2016* (the Charges Act).

**Section 4 – Schedules**

This section gives legal effect to the amendments in the Schedules.

**Schedule 1 – Amendments**

**Items [1 and 3] Subsection 4(1)**

This item repeals the definitions in the Principal Regulations of “cannabis-related manufacture licence”, “commercial cannabis-related manufacture licence” “commercial cannabis research licence”, “medicinal cannabis licence”, “non-commercial cannabis related manufacture licence” and “non-commercial cannabis research licence” because they are no longer required. This follows because of the revised section 54A of the *Narcotic Drugs Regulation 2016* (the Narcotic Drugs Regulation), to be amended by the Medicinal Cannabis Amendment Regulations, which revises the current identification of five classes of licence for the purposes of charge to two classes: a non-commercial medicinal cannabis licence and a commercial medicinal cannabis licence. In turn this is consequential to the Amendment Act provision of a single licence, for any of the activities of cultivation, production or manufacture of medicinal cannabis. The two classes of medicinal cannabis licence are used to identify licences for the purposes of:

- imposition of charge by subsection 6(1) of the Charges Act; and
- the prescription of the amount of charge for subsection 8(1) of the Charges Act.

**Items [2 and 4] Subsection 4(1)**

These items insert new definitions, “commercial medicinal cannabis licence” and “non-commercial medicinal cannabis licence” by identifying them by reference to the definitions in the Narcotic Drugs Regulation. This follows because of the revised section 54A to be amended by the Medicinal Cannabis Amendment Regulations which revises the current identification of five classes of licence for the purposes of charge to two classes: a non-commercial medicinal cannabis licence and a commercial medicinal cannabis licence. In turn, this is consequential to the Amendment Act provision of a single licence, for any of the activities of cultivation, production or manufacture of medicinal cannabis. The two classes of medicinal cannabis licence are used to identify licences for the purposes of:

- imposition of charge by subsection 6(1) of the Charges Act; and
- the prescription of the amount of charge for subsection 8(1) of the Charges Act.

#### **Items [5 and 7] Paragraphs 5(1)((a) to (e) and paragraphs 6(1)(a) to (e)**

Reflecting, for the purposes of imposition of charge by subsection 6(1) of the Charges Act and the amount of that charge for subsection 8(1) of the Charges Act, the revised identification of classes of licence, from five classes to two (commercial and non-commercial kinds of medicinal cannabis licence), these items repeal paragraphs 5(1)(a) to (e) and paragraphs 6(1)(a) to (e) and replace them (for each of subsection 5(1) and 6(1)) with new paragraphs (a), commercial medicinal cannabis licence, and (b) non-commercial medicinal cannabis licence.

#### **Item [6] Subsection 5(2)**

This item repeals existing subsection 5(2) and substitutes new subsection 5(2) to identify the licence year by reference to which subsection 6(1) of the Charges Act imposes a charge on licences. The revised subsection 5(2) is consequential to the three following provisions in the Amendment Act:

- the provision of a single licence, for any of the activities of cultivation, production or manufacture of medicinal cannabis,
- the preservation of one licence in existence at commencement of the Amendment Act as a single medicinal cannabis licence
- the conversion of multiple licences to a single medicinal cannabis licence.

Specifically, there are three possible circumstances which identify the licence year for the medicinal cannabis licence. First, new paragraph 5(2)(a) provides that for a medicinal cannabis licence which is preserved by item 2 of Schedule 2 to the Medicinal Cannabis Amendment Act, the licence year is 12 months starting on either the day the licence came into force or a later anniversary of the day that the licence came into force.

Accordingly, if the preserved licence came into force on 1 March 2021, the licence year is 12 months starting on 1 March 2021 and ending on 28 February 2022 or, subsequent to this licence year the next licence year is 12 months starting on 1 March 2022 and ending on 28 February 2023.

New paragraph 5(2)(b) provides for the second circumstance, a medicinal cannabis licence which was converted from multiple licences (the *original licences*) into a single licence by item 3 of Schedule 2 to the Medicinal Cannabis Amendment Act. It provides a clear and effective realignment of the previously existing different licence years of the separate original licences to specify the converted licence’s licence year. In this case, the licence year is either the 12 months ending immediately before the earliest anniversary day for one of the original licences to occur after the commencement of the Medicinal Cannabis Amendment

Regulations (as identified by reference to new subsection 5(3)) or 12 months starting on a later anniversary of the earliest anniversary day for one of the original licences to occur after the commencement of the Medicinal Cannabis Amendment Regulations.

Accordingly, if the medicinal cannabis licence was converted from a manufacturing licence which came into force on 1 March 2021 and a cannabis licence authorising production activities with an anniversary day on 1 August 2021, the licence year for the converted medicinal cannabis licence is worked out as follows. Using new subsection 5(3) (see below), the anniversary day for the original manufacturing licence is the day immediately following the last day of the licence year for that licence, that is 1 March 2022 and the anniversary day for the original cannabis licence authorising production activities is 1 August 2022. The earliest anniversary day after the commencement of the Medicinal Cannabis Amendment Regulations for the two licences is therefore 1 March 2022. It follows that the licence year to which paragraph 5(2)(b) gives effect is 12 months ending immediately before 1 March 2022, that is 1 March 2021 to 28 February 2022 or, subsequent to this licence year the next licence year would be 12 months ending on 28 February 2023 (and starting on 1 March 2022).

The third circumstance for which the licence year is identified is for the balance of licences (which is not identified by paragraphs 5(2)(a) and (b)), being 12 months starting on either the day on which the licence comes into force or a later anniversary day of the day the licence comes into force.

Accordingly, if a medicinal cannabis licence were to come into force on 1 March 2022 the licence year is 12 months starting on that day or, subsequent to this licence year, is 12 months starting on 1 March 2023.

The item also includes new subsection 5(3) which, for the purposes of subparagraph 5(2)(b)(i), identifies the anniversary day for an original licence as the day immediately after the last day of a licence year for that licence had both the licence year been determined under subsection 5(2) of this instrument as in force before the commencement of the *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021* and the licence had not been converted under item 3 of Schedule 2 to the Amendment Act.

#### **Item [8] Subsection 6(2)**

Consequential to the addition of new subsection 6(7) providing for the limit on charge on commercial medicinal cannabis licences which were converted from multiple licences, this item has the effect that the subsections to which the amount of charge calculated under subsection 6(2) are subject are expanded from subsections (5) and (6) to now include subsection (7).

#### **Item [9] Subsections 6(5) and (6)**

This item repeals existing subsections 6(5) and (6) and substitutes replacement subsections 6(5) and (6) and new subsection 6(7). Each imposes a limit on charge, in the case of the replacements, on non-commercial medicinal cannabis licences. Specifically, the replacements (for subsections 6(5) and (6)) reflect the terminology introduced by section 54A of the Medicinal Cannabis Amendment Regulations specifying as one class of medicinal cannabis licence (of two possible classes) for the purposes of charge, a non-commercial medicinal cannabis licence. New subsection 6(7) imposes a limit on charge on commercial medicinal cannabis licences that were converted from multiple licences.

Revised subsection 6(5) clarifies that charge, imposed by paragraph 6(2)(a) (read with subsection 8(1) of the Charges Act), on a non-commercial medicinal cannabis licence applies only for the licence year starting on the day the licence comes into force.

Revised subsection 6(6) clarifies that charge, imposed by paragraph 6(2)(b) (read with subsection 8(1) of the Charges Act), on a non-commercial medicinal cannabis licence applies only for the first licence year during which one or more permits granted to the holder of the licence and relating to an activity that is authorised by the licence are in force.

The limit on charge on commercial medicinal cannabis licences that were converted from multiple licences that is imposed by new subsection 6(7) will be a function of the effect of the ‘realignment’ of the licence year for the converted licence which is given effect by paragraph 5(2)(b).

Specifically, if, without the operation of subsection 6(7), the application of subsection 5(2)(b) (read with subsection 6(1) of the Charges Act and subsection 6(2)(b) (read with subsection 8(1) of the Charges Act)) has the effect that charge for the same permits granted to the licence holder are imposed and payable twice during the financial year 2021/2022 (the second such occurrence being after the commencement date and on or before the end of the financial year on 30 June 2022), subsection 6(7) has the effect of limiting the imposition and requirement to pay charge for those permits to a single contribution. This outcome is given effect by, relevantly, limiting the application of the ‘second’ charge which would otherwise apply in the financial year 2021/2022 to a licence year that starts on or after 1 July 2022.

The imposition of charge which is, for the converted licence, payable twice during the financial year arises because of the existence of two circumstances. The first circumstance is, by the operation of existing subsection 5(2), that the licence year for one (or more) of the original licences for which there is a permit commenced after 1 July 2021 and before the commencement of the *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021* (see paragraph 6(7)(b)). The second circumstance is, by the operation of revised paragraph 5(2)(b), the licence year for a second (or more) original licence (for which there may be no permits) ends after the commencement and on or before the end of the financial year on 30 June 2022 (see paragraph 6(7)(c)).

Returning to the example of earlier illustrating the application of proposed subsection 5(2)(b) to determine the licence year of a medicinal cannabis licence which was converted from a manufacture licence which came into force on 1 March 2021 and a cannabis licence authorising production activities and for which the anniversary day was 1 August 2021 – in this case where the manufacturing licence had no permits at the beginning of the licence year and the cannabis licence authorising production activities had two permits.

For the cannabis licence authorising production activities (with permits) the applicable (permit) charge, \$19,230, is payable, in accordance with subsection 6(2)(b)(i), for the licence year starting on 1 August 2021. This falls within the criteria specified by paragraph 6(7)(b) as being an amount of charge mentioned in paragraph 6(2)(b) which was applied and was payable by the licence holder in relation to one or more of the original licences during the period beginning on 1 July 2021 and ending on the day before the commencement of subsection 6(7).

Additionally, as earlier explained, new subsection 5(2)(b) has the effect that the licence year for the converted licence is 12 months ending immediately before 1 March 2022, that is 1 March 2021 to 28 February 2022. But for subsection 6(7), subsection 6(2)(b)(i) therefore imposes as payable the charge, \$19,230 for the licence year ending on 28 February 2022. These circumstances fall within the criteria specified by paragraph 6(7)(c), that the anniversary day referred to in subparagraph 5(2)(b)(i) that applies in relation to the licence occurs before 1 July 2022.

Because the circumstances for the converted licence fall within criteria specified by paragraphs 6(7)(b) and (c), subsection 6(7) defers the application of the charge on the commercial medicinal cannabis licence for each licence year that starts on or after 1 July 2022.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

### **Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021**

The *Narcotic Drugs (Licence Charges) Amendment (Medicinal Cannabis Licences) Regulations 2021* (the Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Legislative Instrument**

The Regulations are made under section 9 of the *Narcotic Drugs (Licence Charges) Act 2016*.

The purpose of the Regulations is to amend the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation) to make minor amendments for consistency with the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act), which amended the *Narcotic Drugs Act 1967* (the Narcotic Drugs Act) for various purposes including to introduce a single licence model for medicinal cannabis regulation, in late December 2021.

Specifically, the Regulations, using key terminology to be introduced by the cognate *Narcotic Drugs Amendment (Medicinal Cannabis) Regulations 2021*, provide for a charge for new single licences (and associated permits) to be transitioned by the Amendment Act from the existing licence framework. The Regulations also provide for certain transitional arrangements until the end of the financial year.

#### **Human rights implications**

As the Regulations do not introduce any changes to the Charges Regulation other than to implement the changes outlined above, they do not engage any of the applicable rights or freedoms.

#### **Conclusion**

The Regulations are compatible with human rights as they do not raise any human rights issues.

**Greg Hunt, Minister for Health and Aged Care**