EXPLANATORY STATEMENT

Narcotic Drugs (Licence Charges) Act 2016

Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020

The purpose of the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020* is to update licence charges to implement changes to cost-recovery arrangements for the Office of Drug Control in the Department of Health.

The *Narcotic Drugs (Licence Charges) Act 2016* (the Act) enables the Commonwealth to impose a charge on a medicinal cannabis licence or cannabis research licence granted under the *Narcotic Drugs Act 1967* (the ND Act) and that is in force within a specified period.

Section 9 of the Act provides that the Governor-General may make regulations prescribing all matters that are required or permitted to be prescribed, or which are necessary or convenient to be prescribed to give effect to the Act.

The purpose of the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020* (the Regulations) is to amend the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Principal Regulation) to implement the findings relating to charges of an extensive activity based costing review carried out in late 2019 and early 2020. The review's findings on fees for services are implemented in the *Narcotic Drugs Amendment (Fees) Regulations 2020*, which commence concurrently with the Regulations.

The charging review identified a need to provide for the recovery of the regulatory costs for the efficient administration of the medicinal cannabis regulatory scheme. The review determined the average efficient time spent by a departmental employee across tasks such as generating invoices and undertaking compliance inspections including the differentiation in effort arising from whether the licence holder is still undertaking construction of facilities or is operational under a permit; the former being lower than the latter. The review also identified that costs for inspections of a highly compliant entity can vary from costs for those which are non-compliant.

Accordingly, consistently with the Australia Government Cost Recovery Guidelines, the annual charge reflects the administrative costs associated with the regulation of cannabis licences differentiating between a licence holder still undertaking construction of facilities and another which is operational under a permit, as well as differentiating according to the compliance history of a licence holder.

Specifically, a *licence* charge is incurred by all holders of a medicinal cannabis licence or a cannabis research licence, immediately after grant of the licence and, other than for a non-commercial cannabis research licence, for each year thereafter. The licence charge recovers the costs of administrative operations of the Office of Drug Control in the Department of Health, response to mandatory reporting and inspections as the result of a tip off.

A *site* charge, specifically a charge for a permit authorising the activities to be carried out under a medicinal cannabis licence or a cannabis research licence at a relevant site, is incurred by a licence holder following grant of a permit and consequential site inspection and, other than for the holder of a non-commercial cannabis research licence, for each year following. The site charge recovers the costs of compliance monitoring inspection for the site

or facility, response to mandatory reporting, sampling of cannabis during an inspection, response to regular reporting by licence holders and education and corrective action of licence holders.

Further, an hourly charge is imposed to recover the cost of compliance activities. This places an extra cost on licensees requiring a higher level of monitoring and provides an incentive to encourage compliance. This avoids cross subsidisation where compliant licensees cross subsidise the costs of non-compliant licensees.

The Regulations only extend to medicinal cannabis licences and cannabis research licences and related permits and have no implications for applications for licences or permits for the manufacture of either cannabis or other narcotics.

The Department of Finance was consulted and agreed to the cost recovery model, on the basis that it complied with Australia Government Cost Recovery Guidelines, which is reflected in the Regulations. A cost recovery implementation statement was prepared in relation to the applicable licence charges. The Office of Drug Control (ODC) within the Department of Health hosted six engagement sessions with interested parties from November 2019 to early February 2020. The sessions covered findings from the review of the Medicinal Cannabis Cost Recovery Framework and sought feedback on proposed changes to the fees and charges under the ND Act. Stakeholders, including industry representatives, regulatory consultants and State and Territory government officials attended the public meetings and made submissions to the review. A consultation paper was also published by the ODC in early February 2020, seeking public feedback on the outcomes of the cost recovery review and proposed changes to fees and charges. The feedback at both the public forums and in written submissions was generally supportive of the changes. Feedback was provided acknowledging that the imposition of fees and charges on non-commercial research licence holders should be carefully considered so as not to unduly burden such entities or have an inhibiting effect on research. This matter has been considered and addressed in the revised cost model. The medicinal cannabis industry sector has acknowledged that a more robust cost recovery framework will provide the appropriate level of resources to regulate the scheme.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations is a legislative instrument for the purposes of the *Legislation Act 2003* and commence on 15 July 2020.

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

ATTACHMENT

Details of the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No.1) Regulations 2020*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No.1) Regulations 2020.*

Section 2 – Commencement
This section provides for the commencement of the Regulations on 15 July 2020.

Section 3 – Authority
This section provides that the Regulations are made under the *Narcotic Drugs (Licence Charges) Act 2016* (the Act).

Section 4 – Schedules
This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

Schedule 1 – Amendments

Narcotic Drugs (Licence Charges) Regulation 2016

Item 1
This item amends section 4 of the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Principal Regulation) to provide for a new subsection (1) by which terms are defined.

Item 2
This item provides for two new definitions: 'licence year' defined to have the meaning given by subsection 5(2) of the Regulations and 'Regulatory Powers Act', the *Regulatory Powers (Standard Provisions) Act 2014*.

The Note explains to the reader that subsection 4(2) deals with references to the provisions of the Regulatory Powers Act.

Item 3
This item amends the Principal Regulation to introduce a new subsection (2) providing that a reference to a provision of the Regulatory Powers Act is a reference to that provision as it applies because of Chapter 4 of the *Narcotic Drugs Act 1967* (the ND Act).

Item 4
This item repeals sections 5 and 6 of the current Principal Regulation and substitutes a new section 5 and new section 6. New subsection 5(1) provides that section 5 prescribes, for each of the classes of medicinal cannabis licences, commercial cannabis research licences and non-commercial cannabis research licences, periods during which the licence is in force in relation to which paragraph 6(1)(b) of the Act imposes a charge.

Subsection 5(2) prescribes an annual period, the ***licence year***, on the basis of when the licence comes into force rather than on a financial year basis. That is, for each of these three licences the prescribed period is 12 months commencing on the day that the licence came into force or immediately after the end of the immediately preceding period under this subsection for the licence. If, for example, a licence commenced on 29 February 2020, the initial prescribed period expires on 1 March 2021. Because of the operation of section 2G of the *Acts Interpretation Act 1901* (which is about working out periods of months) each subsequent period expires on 1 March of the relevant year, even in a leap year.

As noted, this item also repeals section 6 of the current Principal Regulation and, for the purposes of subsection 8(1) of the Act, substitutes a new section 6 which prescribes the amount of charge for each of the classes of medicinal cannabis licences, commercial cannabis research licences and non-commercial cannabis research licences.

Subsection 6(2) prescribes the amount of charge on a licence for a licence year is (subject to subsections (5) and (6)) the total of the components specified by paragraphs 6(2)(a), (b) and (c).

Paragraph 6(2)(a) prescribes one component of the amount of the charge on medicinal cannabis licences or commercial cannabis research licences for a licence year (as is defined by subsection 5(2)) as $11,570.

That paragraph, working with subsection 6(5), also prescribes, for a non-commercial cannabis research licence, the fee of $11,570 but only for the licence year which starts on the day the licence comes into force. In effect, there is, for a non-commercial cannabis research licence, only one charge for the first licence year when such a licence is in effect. It is appropriate to impose the charge once. Recurrent charges have a disincentive on research, particularly research undertaken by non-commercial research bodies. Charges on non-commercial cannabis research licence are therefore sufficiently low to encourage and facilitate more research.

There are two effects of paragraph 6(2)(b) which determine the second component of the amount of charge for a licence year; first, for medicinal cannabis licences and commercial cannabis research licences and second, for non-commercial cannabis research licences.

Accordingly, first, paragraph 6(2)(b) prescribes, for any permits in force at any time during the licence year, and in circumstances where any of the permits was in force at the start of the licence year, a component charge of $19,160. If, however, all of the permits came into force after the start of the licence year, the charge is a pro-rated amount of $19,160 in accordance with the formula in subsection (3); that is, it is the amount worked out by multiplying $19,160 by the factor worked out under subsection 6(3).

The factor for which subsection 6(3) provides is the amount worked out using the formula which is the proportion of a licence year for which the licence is in force.

Second, paragraph 6(2)(b), working with subsection 6(6), has the effect of restricting the component charge worked out under paragraph 6(2)(b) for a non-commercial cannabis research licence to the first licence year during which one or more permits granted to the holder of the licence relating to the activity that is authorised by the licence are in force. This

restriction is for the same reasons given in relation to the operation of paragraph 6(2)(a) working with subsection 6(5).

Paragraph 6(2)(c) prescribes the third component charge for an activity covered by subsection 6(4) carried out during the licence period – as $107 for each person carrying out the activity for each hour or part of hour the person spends carrying out that activity and the costs and reasonable expenses of travel to carry out the activity for each such person.

Subsection 6(4) covers each of the following activities:

(a) monitoring, or obtaining information or documents for monitoring, whether an activity authorised by a licence is being, or has been, carried out as authorised (whether or not the monitoring, or obtaining of information or documents, involves the exercise of powers under Part 2 of the Regulatory Powers Act);

(b) investigating a suspected or actual contravention of the *Narcotic Drugs Act 1967*, or regulations made under that Act, relating to a licence (whether or not the investigating involves the exercise of powers under Part 3 of the Regulatory Powers Act);

(c) testing, or certifying the results of testing, of a sample taken:

(i) in accordance with a condition of a licence; or

(ii) in the exercise of power under Part 2 or 3 of the Regulatory Powers Act in relation to a licence; or

(iii) in the exercise of power under section 24 of the *Narcotic Drugs Act 1967* in relation to a licence;

(d) preparing to take action under Part 5, or 6 of the Regulatory Powers Act in relation to the holder of a licence.

The note explains to the reader that whether an activity authorised by a licence is carried out as authorised (as per the terms of paragraph 6(4)(a), for example) may depend on the terms of a permit relating to the activity.

Item 5

This item provides for the application of the Principal Regulation as amended by the Regulations as follows. The Note identifies for the reader that the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020* commenced on 15 July 2020.

(1) This section applies provisions of this instrument as amended by the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020*.

(2) Subsection 5(2) applies in relation to a licence that came or comes into force before, on or after 15 July 2020.

(3) Paragraphs 6(2)(a) and (b) apply to charge for licence years that start on or after 15 July 2020.

(4) Paragraph 6(2)(c) applies to charge for licence years that end on or after 15 July 2020 but does not apply to the carrying out of an activity before 15 July 2020.

(5) This section does not affect the operation of section 7 of the *Acts Interpretation Act 1901* in relation to liability for charge that was incurred before the

commencement of the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020*.

The note explains to the reader that section 7 of the *Acts Interpretation Act 1901* preserves the liability despite the amendments made by the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020*. That section applies in relation to regulations because of section 13 of the *Legislation Act 2003*.

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 (2020 Measures No.1) Regulations 2020
The *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No.1) Regulations 2020* (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 Subsection 5(1) of the *Narcotic Drugs (Charges) Act 2016* (the Act).

The purpose of the Regulations is to amend the *Narcotic Drugs (Charges) Regulation 2016* (the Principal Regulation) to implement the findings relating to charges of an extensive activity based costing review carried out in later 2019 and early 2020. The review's findings on fees for services are implemented in the Regulations.

The costing review identified a need to provide for the recovery of the regulatory costs for the efficient administration of the medicinal cannabis regulatory scheme. The review determined the average efficient time spent by a departmental employee across tasks such as generating invoices and undertaking compliance inspections including the differentiation in effort arising from whether the licence holder is still undertaking construction of facilities or is operational under a permit; the former being lower than the latter. Costs for inspections of a highly compliant entity can also vary from costs for those who are non-compliant.

Accordingly, consistently with the Australia Government Cost Recovery Guidelines, the annual charge reflects the administrative costs associated with the regulation of cannabis licences differentiating between a licence holder still undertaking construction of facilities and another which is operational under a permit as well as differentiating according to the compliance history of a licence holder.

Specifically, a *licence* charge is incurred by all holders of a medicinal cannabis licence or a cannabis research licence immediately after grant of the licence and, apart from the holder of a non-commercial cannabis research licence, for each year thereafter. The licence charge recovers the costs of administrative operations of the Office of Drug Control in the Department of Health, response to mandatory reporting and inspections as the result of a tip off.

A *site* charge, specifically a charge for a permit authorising the activities to be carried out under the a medicinal cannabis licence or cannabis research licence at a relevant site, is incurred by the licence holder following grant of a permit and consequential site inspection and, apart from the holder of a non-commercial cannabis research licence, for each year following. The site charge recovers the costs of compliance monitoring inspection for the site or facility, response to mandatory reporting, sampling of cannabis during an inspection, response to regular reporting by licence holders and education and corrective action of licence holders.

Further, an hourly charge is imposed to recover the cost of compliance activities as well as the costs and reasonable expenses of travel to carry out the activity for each such person. This places an extra cost on licensees requiring a higher level of monitoring and provides an incentive to encourage compliance. This avoids cross subsidisation where compliant licensees cross subsidise the costs of non-compliant licence holders.

Human rights implications

As the Regulations do not introduce any changes to the Principal 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