EXPLANATORY STATEMENT

Narcotic Drugs (Licence Charges) Act 2016

Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023

The *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023* (the Regulations) amend the charges prescribed by the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation), to better support recovery of the costs of administering the medicinal cannabis regulatory scheme under the *Narcotic Drugs Act 1967* (the ND Act).

The *Narcotic Drugs (Licence Charges) Act 2016* (the Act) imposes charge on medicinal cannabis licences that are granted under the ND Act, and which are in force at a specified time. Charges are payable by the holder of the licence.

Section 9 of the Act provides that the Governor-General may make regulations prescribing matters that are required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Section 8 provides that the amount of a charge is the amount prescribed by, or worked out in accordance with a method prescribed by, the regulations.

The purpose of the Regulations is to implement a revised cost recovery model for the Office of Drug Control (the ODC), within the Department of Health and Aged Care, to recover the costs of administering the medicinal cannabis regulatory scheme under the ND Act (the Scheme).

This revised costing model is the result of the Medicinal Cannabis Program Regulatory Fees and Charges Review, being an extensive review of the existing activity-based cost recovery arrangements for the Scheme undertaken in 2022. A key finding of the review was that the current fees do not reflect the level of regulatory effort (and associated costs) required of the ODC to administer the Scheme. This is primarily because of significant reforms to the Scheme, which commenced in December 2021, to implement recommendations of the independent 'Review of the Narcotic Drugs Act 1967' undertaken by Prof John McMillan AO in 2019 (the McMillan Review), the effect of which was to introduce a single licence, an amended permits framework and other changes.

The Regulations make a number of changes to ensure that the cost recovery arrangements align with the Australian Government Charging Framework (the AGCF).

Specifically, the Regulations:

- replace the annual site charge and the hourly rate charge, that are prescribed in respect of monitoring and compliance activities, with two new specific, inspection-related charges (one for routine, compliance inspections and one for verification inspections) and a revised annual licence charge; and
- increase the annual licence charge that is imposed on medicinal cannabis licence holders, to ensure that the charge covers the cost of the entire suite of regulatory activities the ODC undertakes.

The Regulations complement the *Narcotic Drugs Amendment (Fees) Regulations 2023*, which implement the fees-related measures of the ODC's revised costing model.

Details of the Regulations are set out in the Attachment A.

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

The Regulations are a disallowable legislative instrument for the purposes of the *Legislation Act 2003*. The Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

The Regulations commence on 1 August 2023.

Consultation

The ODC undertook public consultation to obtain broader stakeholder feedback in relation to the revised costing model. A public consultation was conducted between 19 December 2022 and 10 February 2023, with feedback and submissions sought on a consultation paper published on the ODC's website. Two information webinars were held during this period and attended by industry participants, industry representative bodies, regulatory consultants, and State and Territory government officials.

Feedback received by the ODC was generally positive. In particular, respondents acknowledged the need to revise the cost recovery arrangements for the medicinal cannabis regulatory scheme to better align with the single licence framework and permit reforms that were implemented by the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* which implemented certain recommendations of the McMillan Review. Following the consultation process, as a result of comments provided by the Department of Finance (in particular to include revised salary amounts), minor increases were made to all associated fees and charges (from that provided during the public consultation) for 2023-24.

ATTACHMENT A

Details of the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023*

Section 1 – Name

This section provides that the title of the Regulations is the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 August 2023.

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 the 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 instrument has effect according to its terms.

Schedule 1 – Amendments

Part 1—Amendments

Narcotic Drugs (Licence Charges) Regulation 2016

The *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation) is made under section 9 of the Act. It prescribes the amounts of charge imposed on a medicinal cannabis licence in a '*licence year*', as that term is defined in the Charges Regulation.

The Charges Regulation complements the *Narcotic Drugs Regulation 2016* (the Principal Regulation), which prescribes fees in respect of the ODC's administration of the medicinal cannabis regulatory scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the ND Act).

On 24 December 2021, amendments to the Act, made by the *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the 2021 Amendments), came into effect to implement certain recommendations from the *Review of the Narcotic Drugs Act 1967* undertaken by Professor John McMillan AO in 2019. The 2021 Amendments implemented a single, perpetual licence model for medicinal cannabis regulation, replacing the previous structure of requiring separate medicinal cannabis licences for different activities. Related permit reforms were also implemented. These broader reforms also resulted in the need for changes to the Scheme's fees, charges, and cost recovery arrangements.

Generally, fees and charges are updated annually, for indexation purposes. However, the fees and charges that are currently prescribed by the Principal Regulation and Charges Regulation have been in place since 1 July 2021. The extended application of the 2021-22 fees and charges was intended to provide for a transitional period following changes to the Act that came into effect on 24 December 2021 following the commencement of the 2021 Amendments. Relevantly, these changes included the introduction of a single licence model for medicinal cannabis related cultivation, production and manufacture activities, and a more streamlined application process for medicinal cannabis permits.

During this transitional period, the ODC conducted an extensive review of the existing activity-based cost recovery arrangements for the Scheme, including in relation to the level at which fees and charges are set. The principal purpose of the review was to determine whether the existing cost recovery arrangements for the Scheme are consistent with the Australian Government Charging Framework (the AGCF), following the 2021 Amendments. Specifically, whether the fees and charges (including the amounts at which they are set) align with the revised legislative framework, and accurately reflect the minimum efficient costs of administering the Scheme. In doing so, it became evident that a number of medicinal cannabis related activities are not (or are not adequately) cost recovered by the fees and charges prescribed by the regulations.

To address these deficiencies, the ODC has developed a revised cost recovery model for the Scheme (the revised costing model). The revised costing model is more aligned with the AGCF and the Australian Government Cost Recovery Guidelines, which, collectively, set out the overarching framework under which government agencies design, implement, and review cost recovered activities that are provided on behalf of the Australian Government.

The Regulations amend the Charges Regulation to give effect to the charges-related measures of the revised costing model. In doing this, the Regulations remove:

- the annual site charge that is currently prescribed by paragraph 6(2)(b) of the Charges Regulation; and
- the hourly rated compliance and monitoring related charges that are currently prescribed by paragraph 6(2)(c) of the Charges Regulation for activities specified in subsection 6(4) of the same instrument.

In effect, these charges are replaced by the charges prescribed in this Schedule.

Item [1] – Section 4 (after the heading)
This item introduces a note after the heading in section 4 of the Charges Regulation, to make it clear that key terms '*charge*' and '*licence*', as they are used in the Charges Regulation, have the same meaning as in the Act.

Item [2] – Subsection 4(1)
This item introduces seven new definitions in subsection 4(1) of the Charges Regulation.

Most of the new definitions adopt definitions in subsection 4(1) of the ND Act. These include, specifically:

- agency of the Commonwealth, a State or a Territory;
- authorised inspector;
- law enforcement agency;
- medicinal cannabis licence; and

- permit.

However, some definitions are new to the medicinal cannabis legislative framework. New definitions for '*inspection type 1*' and '*inspection type 2*' are introduced to refer to the inspection type that some fees relate to.

'Inspection type 1' means an onsite inspection carried out by an authorised inspector, for the purposes of monitoring a licence holder's compliance with the ND Act, or any instrument that is made under that Act. These inspections are often called routine inspections or compliance inspections. They are generally undertaken on a risk-based approach to regulation having regard to the licence holder's compliance history

'Inspection type 2' means an inspection carried out by an authorised inspector, either onsite or virtually, for the purposes of verifying the accuracy of information that has been provided to the ODC in relation to a licence that is in force. That information may relate to any one or more of the following:

- activities engaged in under, or purportedly under, the licence or a permit that relates to the licence;
- conditions of the licence;
- any other matters relating to the licence, or the holder of the licence; and
- any other matters relating to one or more permits that relate to the licence.

The information that triggers an '*inspection type 2*' may come directly from a licence or permit holder, or it may be provided by any other person (e.g. by way of a 'tip-off'), a law enforcement agency, or an agency of the Commonwealth, a State or a Territory.

Consistent with the application-based inspection that is provided for in section 54 of the Principal Regulation, the inspections covered by proposed new '*inspection type 1*' and '*inspection type 2*' are not limited to those carried out in relation to medicinal cannabis licences and permits. Rather, those terms apply to inspections that are carried out in relation to <u>any</u> licence or permit granted under the ND Act.

Inspections that are covered by these new terms are only carried out in relation to the holders of licences or permits that are 'in force' under the ND Act. However, in accordance with subsection 31(2) of the Principal Regulation, this does not preclude authorised inspectors from conducting inspections in relation to licences or permits that have been suspended by the Secretary. This is because medicinal cannabis licences that are suspended by the Secretary remain in force for the period of the suspension (paragraph 29(1)(c) of the Principal Regulation refers).

Item [3] – Section 6
This item replaces existing section 6 of the Charges Regulation with new section 6. It also inserts new section 6A.

<u>Annual licence charge</u>

New section 6 prescribes the amount of charge on a medicinal cannabis licence for the purposes of subsection 8(1) of the Act.

Specifically, it prescribes:

- in subsection 6(2), for a '*commercial medicinal cannabis licence*' — a charge of $27,520 for a '*licence year*'; and
- in subsection 6(3), for a '*non-commercial medicinal cannabis licence*' — a charge of $27,520 for the first year that the licence is in force.

The terms '*commercial medicinal cannabis licence*' and '*non-commercial medicinal cannabis licence*' have the same meaning as in section 54A of the Principal Regulation. A '*non-commercial medicinal cannabis licence*' is, in effect, a licence that authorises the holder to engage only in medicinal cannabis related activities that are (or are primarily) for medicinal or scientific research, undertaken for a non-commercial purpose. Any other medicinal cannabis licence is a '*commercial medicinal cannabis licence*'. The term '*licence year*' is already defined in subsection 5(2) of the Charges Regulation.

The charge amount of $27,520 is significantly higher than the site charge currently imposed on medicinal cannabis licence holders. One of the ODC's principal findings during its costing review was that the current licence charge does not account for all the direct and indirect costs of administering the Scheme following its significant reform in 2021 to introduce a new single licence and amended permits framework. Specifically, it does not reflect the full suite of regulatory activities that it delivers to industry generally. Such tasks include enquiries management; industry education campaigns; investigation and enforcement; and regulatory governance and policy.

The new licence charge amount has been determined by taking the total of all regulatory costs associated with the annual licence charge, and dividing it by the number of licence holders at 31 March (which was 95 licence holders at 31 March 2023).

However, consistent with the existing cost recovery arrangements, new subsection 6(4) provides that the amount of charge on a '*non-commercial medicinal cannabis licence*' is only payable by the licence holder for the first year the licence is in force. For any later year that the licence is in force, the amount of charge is nil. The partial cost recovery arrangements in respect of these types of licences has not been amended in implementing the revised cost recovery model. This reflects that recurrent charges disincentivise research, particularly research undertaken by non-commercial research bodies, which hinders efforts to advance public health through innovation.

New inspection charges

New section 6A prescribes amounts of charge for inspections carried out in relation to a licence that is in force under the ND Act.

Specifically, it prescribes:

- in subsection 6A(2), for an '*inspection type 1*' — a charge of $12,600; and
- in subsection 6A(3), for an '*inspection type 2*' — a charge of $4,760.

Definitions for the terms '*inspection type 1*' and '*inspection type 2*' are added to subsection 4(1) of the Charges Regulation, in accordance with item [2] of the Regulations.

These charges are separate to the fee prescribed by the Principal Regulation for inspections that are carried out in connection with an application for a medicinal cannabis licence or

medicinal cannabis permit (or variation of the same). The charges prescribed by new section 6A apply to inspections that are carried out by the ODC after a licence has been granted (i.e. for the purposes of monitoring compliance or verifying information provided in relation to the licence).

Licence holders that are the subject of an '*inspection type 1*' or '*inspection type 2*' are invoiced at the time the inspection is conducted. The amount of charge specified in the invoice is due and payable to the Secretary, on behalf of the Commonwealth, on the day specified in the invoice.

If more than one inspection is carried out in relation to a licence holder during a licence year, then the licence holder must pay more than one charge during that year (new subsection 6A(4) refers).

Part 2—Application of amendments

Narcotic Drugs (Licence Charges) Regulation 2016

Item [4] – In the appropriate position in Part 3
This item introduces new section 11 to the Charges Regulation, which provides for the application of the amendments in these Regulations. New section 11 provides that:

- the amendments to section 6, made by the Regulations, apply to licence years that start on or after 1 August 2023; and
- the amendments to section 4 and introduction of section 6A by the Regulations apply to inspections commenced on or after 1 August 2023.

ATTACHMENT B

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 (Charge Amounts) Regulations 2023

The *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023* (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 amend the charges prescribed by the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation), to better support recovery of the costs of administering the medicinal cannabis regulatory scheme under the *Narcotic Drugs Act 1967* (the ND Act).

The *Narcotic Drugs (Licence Charges) Act 2016* (the Act) imposes charge on medicinal cannabis licences that are granted under the ND Act, and which are in force at a specified time. Charges are payable by the holder of the licence.

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The purpose of the Regulations is to implement a revised cost recovery model for the Office of Drug Control (the ODC), within the Department of Health and Aged Care, to recover the costs of administering the medicinal cannabis regulatory scheme under the ND Act (the Scheme).

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The Regulations make a number of changes to ensure that the cost recovery arrangements align with the Australian Government Charging Framework (the AGCF).

Specifically, the Regulations:

- replace the annual site charge and the hourly rate charge, that are prescribed in respect of monitoring and compliance activities, with two new specific, inspection-related

charges (one for routine, compliance inspections and one for verification inspections) and a revised annual licence charge; and

- increase the annual licence charge that is imposed on medicinal cannabis licence holders, to ensure that the charge covers the cost of the entire suite of regulatory activities the ODC undertakes.

The Regulations complement the *Narcotic Drugs Amendment (Fees) Regulations 2023*, which implement the fees-related measures of the ODC's revised costing model.

Human rights implications

As the Regulations do not introduce any changes to the Charges Regulations 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.

Ged Kearney, Assistant Minister for Health and Aged Care