

EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Fees) Regulations 2023

The *Narcotic Drugs Amendment (Fees) Regulations 2023* (the Regulations) amend application fees relating to licences and permits for medicinal cannabis related activities, and fees for related inspections, to better support recovery of the cost of administering the medicinal cannabis regulatory scheme.

The *Narcotic Drugs Act 1967* (the Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961, as in force from time to time. Among other things, the Act establishes a licensing and permit scheme for the cultivation and production of cannabis plants, cannabis and cannabis resin, and the manufacture of cannabis drugs, for medicinal and scientific purposes (the Scheme). The Office of Drug Control (the ODC), which is part of the Department of Health and Aged Care, is responsible for administering the Scheme and the Act generally.

Section 27 of the Act provides for the Governor-General to make regulations prescribing matters 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. Amongst other matters, the regulations may prescribe fees in respect of matters under the Act or the regulations made under the Act.

The *Narcotic Drugs Regulation 2016* (the Principal Regulation) is made under section 27 of the Act. Relevantly, it prescribes fees in respect of:

- applications for medicinal cannabis licences or medicinal cannabis permits, and related inspections; and
- applications for variations of a medicinal cannabis licence or medicinal cannabis permit, and related inspections.

The Regulations amend the Principal Regulation to implement a revised costing model that the ODC has developed in relation to its administration of 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.

Specifically, the Regulations replace the fees that are currently prescribed, with the following new fee structure:

- in relation to applications for:
 - a medicinal cannabis licence — a single fee;
 - a medicinal cannabis permit — four fees (i.e. a separate fee depending on the type of permit sought (i.e. whether it is an initial or subsequent permit), and the types of activities to which it would relate);

- in relation to applications for a variation of:
 - an existing medicinal cannabis licence — four fees (i.e. a separate fee for different variation types);
 - an existing medicinal cannabis permit — three fees (i.e. a separate fee for different variation types).

The fee prescribed for inspections that the ODC carries out in relation to applications for licences and permits under the Act (and their variation) is increased. This reflects the ODC's finding that the current fee does not adequately account for the regulatory costs of conducting those inspections.

The Regulations complement the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023*, which implement the charge related measures of the ODC's revised costing model.

Details of the Regulations are set out in [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. 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 supported the proposal to implement fee structures that better reflect the varying levels of regulatory effort required to process medicinal cannabis permit applications, and applications for a variation of a medicinal cannabis licence or permit. Respondents also 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.

Details of the *Narcotic Drugs Amendment (Fees) Regulations 2023*

Section 1 – Name

This section provides that the title of the Regulations is the *Narcotic Drugs Amendment (Fees) 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 Act 1967* (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 Regulation 2016

The *Narcotic Drugs Regulation 2016* (the Principal Regulation) is made under subsection 27(1) of the Act. It imposes fees for the regulatory activities carried out by the Office of Drug Control (the ODC), a part of the Department of Health and Aged Care, in administering the medicinal cannabis regulatory scheme under the Act (the Scheme).

Specifically, the Principal Regulation imposes fees in respect of applications for:

- a medicinal cannabis licence;
- a medicinal cannabis permit;
- a variation of a medicinal cannabis licence or medicinal cannabis permit.

The Principal Regulation also imposes a fee for inspections of premises that are conducted by the ODC in relation to applications for:

- any licence granted under the Act (including a medicinal cannabis licence);
- any permit granted under the Act (including a medicinal cannabis permit); or
- a variation of such a licence or permit.

The Principal Regulation complements the *Narcotic Drugs (Licence Charges) Regulation 2016* (the Charges Regulation), which is made under the *Narcotic Drugs (Licence Charges) Act 2016* and imposes charges on medicinal cannabis licences.

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 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 activity-based review of the existing cost recovery arrangements, 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 Principal Regulation to give effect to the fees-related measures of the revised costing model. The new fees better reflect the minimum efficient costs of performing the regulatory activities to which they relate.

Item [1] – Section 4

This item introduces the following new definitions relating to licence variations:

- licence variation type 1;
- licence variation type 2;
- licence variation type 3; and
- licence variation type 4.

The purpose of these definitions is to identify the licence variation types that attract a particular fee amount. They replace the current definition for ‘minor licence variation’, to give effect to the revised costing model.

These terms are referred to in table items 6 to 9 of new clause 1 of Schedule 1 to the Principal Regulation. Those table items prescribe the fees for an application under section 10N of the Act for a variation of a medicinal cannabis licence. The applicable fee depends on the type (and number) of variations being applied for.

licence variation type 1 is defined as an application for a variation of a medicinal cannabis licence to:

- vary the name of the person who is the licence holder, without changing the legal entity that is the licence holder, that is:
 - for a body corporate — a change in that entity’s business or trading name;
 - for an individual — a change in that individual’s name (e.g. following marriage or a divorce); or
- vary or remove the name, description under section 7B of the Principal Regulation, or any other description, of a person who is authorised by the licence to engage in the activities that are authorised by the licence.

As illustrated by the examples, a separate fee is payable for each variation, noting that the variations may be covered by the same paragraph or different paragraphs in the definition of ‘licence variation type 1’. For paragraph (b) of the definition of ‘licence variation type 1’, one fee is payable for a change to any of the matters listed in that paragraph where it relates to a particular person. For instance, two fees are payable for changes to any of the matters listed in paragraph (b) that relate to two different people authorised by the licence.

licence variation type 2 is defined as an application for a variation of a medicinal cannabis licence to:

- vary or add the period for which the licence is in force;
- vary, add, or remove, for a particular licenced premises, any one or more measures relating to the system of security that was approved for the grant of the licence or varied after the licence was granted; or
- make any other variation that is not otherwise specified in this definition, or in the definitions of ***licence variation type 1***, ***licence variation type 3***, or ***licence variation type 4***, including, for example:
 - where the licence holder is a body corporate — a variation to reflect a change in the body corporate’s ACN, or to its structure as a public or private company; or
 - vary or remove a particular (single) condition that the Secretary has imposed on the licence under the Act.

A separate fee is payable for each variation, noting that the variations may be covered by the same paragraph or different paragraphs in the definition of ‘licence variation type 2’. As illustrated by the example, two fees are payable for changes to the system of security (covered by paragraph (b) of this definition) for two different licenced premises.

licence variation type 3 is defined as an application for a variation of a medicinal cannabis licence to:

- vary the site plan for particular licensed premises where activities authorised by the licence are undertaken;
- vary one or more floor plans of facilities at particular licensed premises where the activities authorised by the licence are undertaken (without changing the activities authorised by the licence);
- vary, add or remove a particular activity that is to be authorised by the licence at particular licensed premises (including an associated change to the floor plan); or
- add the name of a particular person to be authorised by the licence to engage in the activities that are authorised by the licence at any one or more licensed premises at which the licence authorises activities to be undertaken.

As illustrated by the example, a separate fee is payable for each variation, noting that the variations may be covered by the same paragraph or different paragraphs in the definition of ‘licence variation type 3’.

However, only one fee is payable for a variation to add the name of a particular person to be authorised by the licence to engage in the activities authorised by the licence at more than one licensed premises at which the licence authorises activities to be undertaken. This reflects the fact that often, in circumstances where the licence holder has more than one licensed premises, an authorised person on the licence has responsibilities across more than one premises.

licence variation type 4 is defined as an application for a variation of a medicinal cannabis licence to add a particular licensed premises at which activities authorised by the licence are to be undertaken. Additional variations that are consequential to a variation to add a licensed premises are also covered by the fee prescribed for this licence variation type. For example, there is no additional fee for adding a site plan or floor plan for the new licensed premises.

Items [2] and [3] – Section 4 (definitions of *minor licence variation* and *minor permit variation*)

These items repeal the definitions of ‘*minor licence variation*’ and ‘*minor permit variation*’ in section 4 of the Principal Regulation. As those terms are not referred to in new clause 1 of Schedule 1 to the Principal Regulation, their definitions are redundant.

To align with the revised costing model, these definitions are replaced by the new definitions for the new licence variation types and permit variation types.

Item [4] – Section 4

This item inserts the following new definitions in relation to permit variations:

- permit variation type 1;
- permit variation type 2;
- permit variation type 3; and
- supply pathway.

The purpose of these definitions is to identify the permit variation types that attract a particular fee amount for an application. The terms ‘*permit variation type 1*’, ‘*permit variation type 2*’, and ‘*permit variation type 3*’, are referred to in table items 10 to 12 of new clause 1 of Schedule 1 to the Principal Regulation. Those table items prescribe the fees for an application under section 10N of the Act for a variation of a medicinal cannabis permit, with the applicable fee depending on the type of variation sought. These definitions replace the

current definition of ‘minor permit variation’, in order to give effect to the revised costing model.

permit variation type 1 is defined as an application for a variation of a medicinal cannabis permit to:

- vary the name of the person who is the holder of the licence to which the permit relates, without changing the legal entity that is the licence holder, namely:
 - for a body corporate — a change in that entity’s business or trading name;
 - for an individual — a change in that individual’s name (e.g. following marriage or a divorce); or
- vary any one or more of the following that the licence holder may have in their possession or control at any one time:
 - the maximum number of cannabis plants;
 - the maximum units of seeds,
 - the maximum quantity of cultivars or genetic material of a cannabis plant;
 - the maximum quantity of cannabis, cannabis resin, or cannabis drug,provided the variation does not result in an increase to the total number, units, or quantity that the licence holder is authorised to obtain, cultivate, produce, or manufacture during the period of the permit. A change to the total quantities falls within the definition of ‘*permit variation type 3*’, whereas this definition only captures a change to the maximum quantities.

A separate fee is payable for each variation, noting that the variations may be covered by the same paragraph or different paragraphs in the definition of ‘permit variation type 1’. For paragraph (b) of the definition of ‘permit variation type 1’, one fee is payable for a change to any one or more of the matters listed in that paragraph for a particular permit.

permit variation type 2 is defined as an application for a variation of a medicinal cannabis permit to add or remove a particular ‘*supply pathway*’ that is specified by the permit – with ‘supply pathway’ separately defined.

A separate fee is payable for each variation covered by the definition of ‘permit variation type 2’. For example, if three supply pathways are added, the fee payable is three times the fee for a variation that is a permit variation type 2.

permit variation type 3 is defined as an application for a variation to a medicinal cannabis permit to:

- vary any one or more of the following that the licence holder is authorised to obtain, cultivate, produce, or manufacture during the period of the permit:
 - the types of cannabis plants;
 - the total number of cannabis plants;
 - the total units of seeds;
 - the total quantity of cultivars or genetic material of a cannabis plant;
 - the total quantity of cannabis, cannabis resin, or cannabis drug; or
- vary, add, or remove a particular (single) activity specified by the permit to be undertaken at the relevant licensed premises.

As illustrated by the example, a separate fee is payable for each variation, noting that the variations may be covered by the same paragraph or different paragraphs in the definition of ‘permit variation type 3’. For paragraph (a) of the definition of ‘permit variation type 3’, one

fee is payable for a change to any of the matters listed in that paragraph for a permit. For instance, one fee is payable for changes to any of the matters listed in paragraph (a).

The term **supply pathway** is introduced in section 4 of the Principal Regulation, as it is referred to in the new definition of ‘*permit variation type 2*’. ‘Supply pathway’ is defined to mean an arrangement to supply cannabis plants, cannabis, cannabis resin, or cannabis drug, that is required by the Act, or otherwise specified by a medicinal cannabis licence or medicinal cannabis permit. The arrangement to supply may be the permitted supply (as defined) or the arrangement for supply that is authorised by the permit.

Item [5] – Section 10

This item replaces existing section 10 of the Principal Regulation with new section 10.

For the purposes of subsection 8P(3) of the Act, new section 10 imposes an application fee for a medicinal cannabis permit that authorises:

- either or both the cultivation of cannabis plants, or the production of cannabis or cannabis resin, under subsection 9B(1) or (2) of the Act; or
- the manufacture of a cannabis drug under subsection 9B(3) of the Act.

The fees for these applications are prescribed in table items 2 to 5 (inclusive) of new clause 1 of Schedule 1 to the Principal Regulation.

Item [6] – Section 24

This item replaces existing section 24 of the Principal Regulation with new section 24. For the purposes of subsection 10N(2) of the Act, new section 24 imposes an application fee for variation of medicinal cannabis licences and medicinal cannabis permits.

New subsection 24(2) clarifies, to avoid doubt, that an application under section 10N of the Act may apply for more than one variation of a medicinal cannabis licence or medicinal cannabis permit. As such, licence holders do not need to complete multiple application forms where they are applying for more than one variation to a particular permit or licence. However, in such circumstances, the total fee payable depends on the type and number of variations applied for.

New subsection 24(3) applies in relation to applications for a single variation of a medicinal cannabis licence or medicinal cannabis permit within a particular category of licence or permit variation type (for example, one ‘*licence variation type 1*’). It provides that, in such circumstances, the fee for the application is the amount prescribed by new clause 1 of Schedule 1 for the relevant licence variation type or permit variation type.

New subsection 24(4) applies, to avoid doubt, in relation to an application for a variation of a medicinal cannabis licence or medicinal cannabis permit that contains:

- more than one licence variation type or permit variation type (for example, an application for a ‘*licence variation type 1*’ and ‘*licence variation type 2*’);
- more than one variation within the same licence variation type or permit variation type (for example, two variations that are both a ‘*licence variation type 1*’); or
- a combination of the above.

The fee for an application covered by subsection 24(4) is the total of each of the amounts prescribed by new clause 1 of Schedule 1 for the relevant licence variation types or permit

variation types (or multiple variations covered by a particular paragraph within those variation types). For example, the application fee that is prescribed in table item 6 of clause 1 of Schedule 1 for a *‘licence variation type 1’* is \$580. If a licence holder applies for two licence variations of this type, the application fee is \$1,160. Also, for example, the total fee for an application for two variations, one that is a *‘licence variation type 1’*, and another that is a *‘licence variation type 2’*, is the sum of the amounts prescribed by table items 6 and 7 of new clause 1 of Schedule 1 (i.e. \$2,050).

The revised costing model proposes a ‘building block’ approach to prescribing fees for an application to vary a medicinal cannabis licence or permit. This is because the work effort in assessing particular variations differ depending on the application and its relative complexity, so the building block approach ensures that an applicant pays for the particular variations requested.

Accordingly, subsection 24(4) gives effect to this ‘building block’ approach by prescribing that the application fee payable is the sum of the individual fees for each variation that is requested in the application.

For example, if an application is made for:

- a variation that is a *‘licence variation type 3’* to add a person authorised to undertake the activities authorised by the licence (at \$2,170), and
- another variation that is a *‘licence variation type 1’* to remove a person from the licence (at \$580),

the application fee is \$2,750.

Also, for example, if a licence variation application to change a floor plan at licenced premises also requires changes to previously approved security measures for that particular licenced premises, this involves a *‘licence variation type 3’* (at \$2,170) and a *‘licence variation type 2’* (at \$1,470) respectively, so the application fee is a total of \$3,640.

If a licence authorising cultivation and production activities, to be undertaken at a particular licenced premises, is to be varied to add manufacturing as a new activity that is authorised by the licence to be undertaken at that premises, an application for a variation that is a *‘licence variation type 3’* is required at a cost of \$2,170. This includes the cost of varying the floor plan of the facilities at that licensed premises as a result of adding this new activity. The application also needs to include a variation that is a *‘licence variation type 2’* at \$1,470, to add any additional security measures required. In this example, the application fee for the application to make these variations is \$3,640.

Item [7] – Section 54(1)

This item amends the fee that is prescribed in subsection 54(1) of the Principal Regulation. That is, the fee prescribed for inspections carried out in connection with an application for a licence or permit under the Act, or their variation. The new, increased fee is \$9,230, which better reflects the regulatory effort (and associated costs) required to carry out such inspections.

Items [8] and [9] – Subsections 54B(2) and (3)

These items amend subsections 54B(2) and (3) of the Principal Regulation to clarify that:

- charge payable on a matter that relates to a licence is payable to the Secretary on behalf of the Commonwealth; and

- an amount of charge payable on a matter that relates to a licence is due and payable on the day specified in an invoice for the amount given to the licence holder by the Secretary.

These amendments complement the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023*, which introduce two new inspection-related charges to the Charges Regulation, with the annual charge and each inspection charge being a matter that relates to a licence that is in force.

Item [10] – Clause 1 of Schedule 1

This item replaces existing clause 1 of Schedule 1 to the Principal Regulation with new clause 1 of Schedule 1.

The purpose of this amendment is to introduce a new table of fees in relation to:

- for section 8E of the Act — an application for a medicinal cannabis licence;
- for section 8P of the Act — an application for a medicinal cannabis permit; and
- for section 10N of the Act — an application for each licence variation type and permit variation type.

Medicinal cannabis licence applications

New table item 1 prescribes the fee for a medicinal cannabis licence application.

Currently, the fees prescribed for a medicinal cannabis licence application are specified in table items 1 to 3 of clause 1 of Schedule 1. The applicable fee depends on how many of the activities referred to in paragraphs 8E(1)(a) to (c) of the Act are to be authorised by the licence. That is, whether the licence would permit one or more of the cultivation of cannabis plants, the production of cannabis or cannabis resin, or the manufacture of cannabis drug, for medicinal and scientific purposes.

The effect of new table item 1 is that there is a single fee for all medicinal cannabis licence applications, regardless of how many activities are to be authorised by the licence. This is consistent with the single medicinal cannabis licence framework that was implemented by the 2021 reforms.

The dollar amount of the new fee is \$13,220, which has been costed to reflect the effort required to assess such an application.

Medicinal cannabis permit applications

New table items 2 to 5 (inclusive) prescribe four separate fees for a medicinal cannabis permit application.

Currently, a single fee is prescribed for medicinal cannabis permit applications by table item 4 of clause 1 of Schedule 1. However, a key finding of the ODC’s activity-based review is that the level of regulatory effort (and associated costs) required to process such applications varies according to the type of permit sought (i.e. whether it is an initial or subsequent permit), and the types of activities to which it would relate. As a result, the single fee currently prescribed does not accurately reflect the minimum efficient costs of processing medicinal cannabis permit applications.

The effect of table items 2 to 5 in new clause 1 of Schedule 1 is that the fee for a medicinal cannabis permit application depends on:

- the activities specified in section 9B of the Act to which the permit would relate (i.e. the cultivation of cannabis plants or the production of cannabis or cannabis resin (or both), or the manufacture of cannabis drug); and
- whether the application is the first permit application that has been made by the holder of a licence in relation to a licensed premises for any one or more of the activities specified in section 9B of the Act — that is, whether it is an initial or subsequent application.

The new fees are as follows:

- \$11,910 — for an *initial* application for a medicinal cannabis permit to authorise either or both the cultivation of cannabis plants, or the production of cannabis or cannabis resin at a particular licensed premises;
- \$7,860 — for an *initial* application for a medicinal cannabis permit to authorise the manufacture of a cannabis drug at a particular licensed premises;
- \$9,070 — for a *subsequent* application for a medicinal cannabis permit to authorise either or both the cultivation of cannabis plants, or the production of cannabis or cannabis resin, at a particular licensed premises;
- \$5,980 — for a *subsequent* application for a medicinal cannabis permit to authorise the manufacture of a cannabis drug at a particular licensed premises.

Medicinal cannabis licence and permit variations

New table items 6 to 12 prescribe a fee for each new licence variation type and permit variation type.

The fees that are currently prescribed for medicinal cannabis licence variations are specified in table items 5 and 6 of clause 1 of Schedule 1. The fees that are currently prescribed for medicinal cannabis permit variations are specified in table items 7 and 8 of clause 1 of Schedule 1. In both cases, the applicable fee depends on whether the variation sought is a ‘*minor licence variation*’ or a ‘*minor permit variation*’, as those terms are defined in section 4 of the Principal Regulation. If the variation sought is not covered by those defined terms, then the higher prescribed fee applies.

However, one of the ODC’s principal review findings was that the level of regulatory effort required to process licence and permit variation applications varies greatly according to the nature of the variation sought. This is because there is a broad range of variations that medicinal cannabis licence holders can apply for with respect to their licence or permit, each of which require varying levels of regulatory effort to process. Accordingly, the current categorisation of variation types does not accurately reflect the costs incurred by the ODC in providing the relevant services.

The effect of table items 6 to 9 in new clause 1 of Schedule 1 is that the fee for a licence variation application depends on the licence variation type(s) applied for. These align with the new definitions for the various licence variation types. These definitions categorise specific types of variations based on their associated level of regulatory effort, and a separate fee is payable for each variation applied for, enabling those variations to be appropriately cost recovered.

The new fees for a medicinal cannabis licence variation are as follows:

- \$580 — for each licence variation specified as being a licence variation type 1;
- \$1,470 — for each licence variation specified as being a licence variation type 2;
- \$2,170 — for each licence variation specified as being a licence variation type 3;
- \$11,960 — for each licence variation specified as being a licence variation type 4.

The effect of table items 10 to 12 in new clause 1 of Schedule 1 is that the fee for a permit variation application depends on the permit variation type(s) applied for. These align with the new definitions for the various permit variation types. These definitions categorise specific types of variations based on their associated level of regulatory effort, and a separate fee is payable for each variation to a permit, allowing those variations to be appropriately cost recovered.

The new fees for a medicinal cannabis permit variation are as follows:

- \$620 — for each permit variation specified as being a permit variation type 1;
- \$1,660 — for each permit variation specified as being a permit variation type 2;
- \$5,140 — for each permit variation specified as being a permit variation type 3.

Part 2—Application of amendments

Narcotic Drugs Regulation 2016

Item [11] – In the appropriate position in Part 6

This item adds new section 63 into the Principal Regulation. New section 63 provides that:

- the amendments of section 4, 10 and 24, and clause 1 of Schedule 1, made by the Regulations, apply to applications made on or after 1 August 2023;
- the amendment of subsection 54(1) made by the Regulations apply in relation to inspections that are commenced on or after 1 August 2023; and
- the amendments of subsections 54B(2) and (3), made by the Regulations, apply to inspections commenced on or after 1 August 2023.

Statement of Compatibility with Human Rights

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

Narcotic Drugs Amendment (Fees) Regulations 2023

The *Narcotic Drugs Amendment (Fees) 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 application fees relating to licences and permits for medicinal cannabis related activities, and fees for related inspections, to better support recovery of the cost of administering the medicinal cannabis regulatory scheme.

The *Narcotic Drugs Act 1967* (the Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs, 1961, as in force from time to time. Among other things, the Act establishes a licensing and permit scheme for the cultivation and production of cannabis plants, cannabis and cannabis resin, and the manufacture of cannabis drugs, for medicinal and scientific purposes (the Scheme). The Office of Drug Control (the ODC), which is part of the Department of Health and Aged Care, is responsible for administering the Scheme and the Act generally.

Section 27 of the Act provides for the Governor-General to make regulations prescribing matters 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. Amongst other matters, the regulations may prescribe fees in respect of matters under the Act or the regulations made under the Act.

The *Narcotic Drugs Regulation 2016* (the Principal Regulation) is made under section 27 of the Act. Relevantly, it prescribes fees in respect of:

- applications for medicinal cannabis licences or medicinal cannabis permits, and related inspections; and
- applications for variations of a medicinal cannabis licence or medicinal cannabis permit, and related inspections.

The Regulations are made under subsection 27(1) of the *Narcotic Drugs Act 1967*. The Regulations amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to implement a revised costing model that the ODC has developed in relation to its administration of 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.

Specifically, the Regulations replace the fees that are currently prescribed, with the following new fee structure:

- in relation to applications for:
 - a medicinal cannabis licence — a single fee;
 - a medicinal cannabis permit — four fees (i.e. a separate fee depending on the type of permit sought (i.e. whether it is an initial or subsequent permit), and the types of activities to which it would relate);
- in relation to applications for a variation of:
 - an existing medicinal cannabis licence — four fees (i.e. a separate fee for different variation types);
 - an existing medicinal cannabis permit — three fees (i.e. a separate fee for different variation types).

The fee prescribed for inspections that the ODC carries out in relation to applications for licences and permits under the Act (and their variation) is increased. This reflects the ODC's finding that the current fee does not adequately account for the regulatory costs of conducting those inspections.

The Regulations complement the *Narcotic Drugs (Licence Charges) Amendment (Charge Amounts) Regulations 2023*, which implement the charge related measures of the ODC's revised costing model.

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.

Ged Kearney, Assistant Minister for Health and Aged Care