EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Fees) Regulations 2024

The *Narcotic Drugs Amendment (Fees) Regulations 2024* (the Regulations) increase application fees for licences and permits for activities related to medicinal cannabis, and fees for related inspections, in accordance with the annual indexation of fees to support recovery of the cost of administering the medicinal cannabis regulatory scheme. They also make other minor amendments consequential to the implementation of digital reforms.

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 purpose of the Regulations is, principally, to amend the Principal Regulation to increase the prescribed fees by applying annual indexation for the 2024-25 financial year. The application of annual indexation is intended to ensure appropriate cost recovery of the costs associated with administering the Scheme.

Specifically, the Regulations update and increase the fees that are currently prescribed in the Principal Regulation in relation to:

- inspections of premises conducted in relation to an application; and
- applications for:
    - a medicinal cannabis licence; and
    - a medicinal cannabis permit; and
- applications for a variation of:
    - an existing medicinal cannabis licence; and
    - an existing medicinal cannabis permit.

Under the Regulations, inspection fees increase by a maximum of 1.7%. Licence and permit application fees increase on average by 2.5%. The increase to fees has been determined using an indexation formula based on the relevant work effort to administer the Scheme, and average salary rates for the Department of Health and Aged Care as provided by the Department of Finance.

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The Regulations complement the *Narcotic Drugs (Licence Charges) Amendment Regulations 2024*, which update the regulatory licence charges for licences relating to medicinal cannabis, commercial cannabis research and non-commercial cannabis research to reflect annual indexation for 2024-25.

The Regulations also remove the requirement for natural person applicants to provide certified true copies of identification documents when applying for either a medicinal cannabis or a manufacture licence. The ODC Transformation Program will establish a new digital portal that will streamline the application process for licences under the Act. From 1 July 2024, all natural person applicants will need to use the digital portal when applying for either a medicinal cannabis or a manufacture licence.

Subsections 8E(2) and 11G(2) of the Act require any applications for medicinal cannabis licences and manufacture licences to be made in the form or manner approved in writing by the Secretary of the Department of Health and Aged Care. As all users of the digital portal will only be able to access the portal by being authenticated using their personal myGovID, it would be duplicative for applicants to also provide certified true copies of identification documents. Accordingly, the Regulations amend the Principal Regulation to remove this requirement.

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 legislative instrument for the purposes of the *Legislation Act 2003*. The instrument is compatible with human rights and freedoms recognised or declared under sectino3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.* A full statement of compatibility is set out in Attachment B.

The Regulations commence on 1 July 2024.

Consultation

The ODC undertook extensive stakeholder consultation during the review of the ODC fees and charges in 2022-23, which led to the introduction of a new activities-based costing model in August 2023. Through this consultation, stakeholders were advised that the new framework would include annual indexation of fees and charges.

In February and March 2024, the ODC conducted targeted consultation to inform the medicinal cannabis industry of the proposed increase in fees and charges due to indexation, and to seek feedback. This consultation was undertaken through direct communication channels, including directly to medicinal cannabis licence holders and relevant peak industry bodies, as well as via an update at an industry specific forum. No feedback was provided from the industry in relation to the proposed indexation of fees and charges.

Authority: Subsection 27(1) of the *Narcotic Drugs Act 1967*

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ATTACHMENT A

Details of the *Narcotic Drugs Amendment (Fees) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Narcotic Drugs Amendment (Fees) Regulations 2024.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2024.

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 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 this instrument has effect according to its terms.

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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; and
- 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.

The Regulations amend application fees relating to licences and permits for activities relating to medicinal cannabis, and fees for related inspections, to apply indexation for the 2024-25 financial year to support recovery of the cost of administering the Scheme. The new fees better reflect the minimum efficient costs of performing the regulatory activities to which they relate.

The Regulations also implement minor amendments to streamline the licence application process following the establishment of a new digital portal for the provision of health products services.

Item [1] – Section 4
This item repeals the following definitions:

- category A document;
- category B document;
- certified true copy; and
- identification document.

The purpose of these definitions is to prescribe the various forms of personal identification documentation that must accompany an application for a medicinal cannabis licence or a manufacture licence. Following the establishment of the new digital portal, natural person applicants will instead verify their identity through the myGovID portal. It is duplicative for applicants to also provide certified true copies of identification documents, so certified true

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copies of identification documents will no longer be required. As these terms are no longer referred to in the Principal Regulation, their definitions are redundant.

Items [2] – Paragraph 6(2)(a)
This item repeals paragraph 6(2)(a) of the Principal Regulation, which requires natural person applicants for a medicinal cannabis licence to provide certified true copies of three personal identification documents, at least one of which must be a category A document.

From 1 July 2024, all natural person applicants need to use the digital portal when applying for a medicinal cannabis licence. As all users of the digital portal are only able to access the portal by being authenticated using their personal myGovID, it would be duplicative for applicants to also provide certified true copies of identification documents. Accordingly, this amendment has the effect of removing this requirement.

Item [3] – Paragraph 36(2)(a)
This item repeals paragraph 36(2)(a) of the Principal Regulation, which requires natural person applicants for a manufacture licence to provide certified true copies of three personal identification documents, at least one of which must be a category A document.

From 1 July 2024, all natural person applicants will need to use the digital portal when applying for a manufacturing licence. As all users of the digital portal are only able to access the portal by being authenticated using their personal myGovID, it would be duplicative for applicants to also provide certified true copies of identification documents. Accordingly, this amendment has the effect of removing this requirement.

Item [4] – Subsection 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 fee is $9,370, which is an increase to the current fee in accordance with annual indexation and better supports cost recovery of the Scheme.

Item [5] – In the appropriate position in Part 6
This item introduces new section 64 to the Principal Regulation. New section 64 provides that:

- the amendment of subsection 54(1) made by the Regulations applies in relation to inspections that are commenced on or after 1 July 2024; and
- the amendments of clause 1 of Schedule 1 made by the Regulations, applies to applications made on or after 1 July 2024.

Item [6] – Clause 1 of Schedule 1
This item replaces existing fees that are prescribed in column 2 of the table in clause 1 of Schedule 1 to the Principal Regulation with an increased fee in accordance with annual indexation.

Table item 1 prescribes the new fee for an initial application for a medicinal cannabis licence under section 8E of the Act, which is $13,560.

Table items 2 to 5 (inclusive) prescribe fees associated with medicinal cannabis permit applications. The new fees for a medicinal cannabis permit are as follows:

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- $12,110 — 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;
- $8,000 — for an *initial* application for a medicinal cannabis permit to authorise the manufacture of a cannabis drug at a particular licensed premises;
- $9,270 — 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;
- $6,120 — for a *subsequent* application for a medicinal cannabis permit to authorise the manufacture of a cannabis drug at a particular licensed premises.

Table items 6 to 9 (inclusive) prescribe fees for medicinal cannabis licence variation applications. The new fees for a medicinal cannabis licence variation are as follows:

- $595 — for each licence variation specified as being a licence variation type 1;
- $1,510 — for each licence variation specified as being a licence variation type 2;
- $2,220 — for each licence variation specified as being a licence variation type 3;
- $12,280 — for each licence variation specified as being a licence variation type 4.

Table items 10 to 12 (inclusive) prescribe fees for medicinal cannabis permit variation applications. The new fees for a medicinal cannabis permit variation are as follows:

- $630 — for each permit variation specified as being a permit variation type 1;
- $1,690 — for each permit variation specified as being a permit variation type 2;
- $5,250 — for each permit variation specified as being a permit variation type 3.

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ATTACHMENT B

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 2024

The *Narcotic Drugs Amendment (Fees) Regulations 2024* (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

Section 27 of the *Narcotic Drugs Act 1967* (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.

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The purpose of the Regulations is, principally, to amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to increase the prescribed fees by applying annual indexation for the 2024-25 financial year. The application of annual indexation is intended to ensure appropriate cost recovery of the costs associated with administering the Scheme.

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Under the Regulations, inspection fees increase by a maximum of 1.7%. Licence and permit application fees increase on average by 2.5%. The increase to fees has been determined using an indexation formula based on the relevant work effort to administer the Scheme, and average salary rates for the Department of Health and Aged Care as provided by the Department of Finance.

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Subsections 8E(2) and 11G(2) of the Act require any applications for medicinal cannabis licences and manufacture licences to be made in the form or manner approved in writing by the Secretary of the Department of Health and Aged Care. As all users of the digital portal will only be able to access the portal by being authenticated using their personal myGovID, it would be duplicative for applicants to also provide certified true copies of identification documents. Accordingly, the Regulations amend the Principal Regulation to remove this requirement.

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

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