EXPLANATORY STATEMENT

Narcotic Drugs Act 1967

Narcotic Drugs Amendment (Fees) Regulations 2020

The purpose of the *Narcotic Drugs Amendment (Fees) Regulations 2020* (the Regulations) is to update fees to implement changes to cost-recovery arrangements for the Office of Drug Control in the Department of Health.

The *Narcotic Drugs Act 1967* (ND Act) gives effect to certain of Australia's obligations under the Single Convention on Narcotic Drugs 1961 (the Convention), as in force from time to time. The objective of the Convention is to establish a framework to both prevent abuse and diversion of controlled narcotics and to ensure the availability of such drugs for medical and scientific purposes.

The Regulations implement the findings relating to fees of an extensive activity based costing review of fees and charges under the ND Act carried out in late 2019 and early 2020. The review's findings on charges are implemented in the *Narcotic Drugs (Licence Charges) Amendment (2020 Measures No. 1) Regulations 2020*, which commence concurrently with these Regulations.

The principal fees related measure identified in the costing review was that the existing fees do not adequately recover the costs for the work the Department of Health carries out in considering applications for licences and permits. The review determined the average efficient time spent by a departmental employee across tasks such as generating invoices, assessing licence applications and permit applications, including the differentiation in effort arising from the complexity of an application. Further, it determined that the effort required for the inspection of land or premises that is conducted in relation to an application should not vary in effort from one location to another.

The Regulations are made under subsection 27(1) of ND Act and amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to provide for the adequate recovery of the costs for the work the Department of Health carries out in considering applications for licences and permits and in conducting related inspections. Specifically, the Regulations provide for the following for medicinal cannabis licences and cannabis research licences:

- Introduce a fee structure which would reflect the number of *medicinal cannabis licence* and *cannabis research licence* applications submitted as follows:
    - single licence application;
    - *concurrent* applications for *two* licences at the same site;
- Reflecting its unnecessity following this new fee structure for concurrent applications for licences, the repeal of section 53 providing for 75% reduction for concurrent applications;
- Introduce a fee structure for applications to *vary* a *medicinal cannabis licence* or a *cannabis research licence* as follows:
    - *simple variation* – one example of which would be to vary the licence to change the trading name of the licence holder;
    - *complex variation* – one example of which would be to vary the licence to expand an existing licensed site or facility to include new cultivation or production areas or adding a new site or facility to an existing licence.

For medicinal cannabis permits and cannabis research permits

- Introduce a fee structure for applications to *vary a permit* as follows:
    - *simple variation* – one example of which would be an application to vary the permit to increase the maximum size of a cannabis crop *only* if that application does not require a variation to any other aspect of the permit;
    - *complex variation* – one example of which would be an application to vary the permit to vary the types and strains of cannabis or cannabis plants that may be cultivated.

The fees for licence and permit variations are given effect is by way of the Regulations referencing an administrative instrument published on the Department of Health's website. The ND Act authorises the regulations to make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other document despite section 14 of the *Legislation Act 2003*. The relevant instrument is freely accessible and free for use.

The Regulations and the measures above 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 *Narcotic Drugs Act 1967* specifies no conditions that need to be satisfied before the power to make the Regulation may be exercised.

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

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

ATTACHMENT

Details of the *Narcotic Drugs Amendment (Fees) Regulations 2020*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Narcotic Drugs Amendment (Fees) 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 Act 1967* (the ND 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 Regulation 2016

Item 1
This item amends section 4 of the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to provide for the addition of one new defined term:

variation application classification document means the document, *Specification of variation applications*, published on the website of the Department of Health, as in force from time to time. It classifies whether a variation application is simple or complex and is incorporated by reference in items 4, 5, 6 and 7 of the table in clause 1 in Schedule 1 by which relevant fees are prescribed. This is in accordance with the authority of subsection 28(2) of the ND Act which authorises the regulations to make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other document despite section 14 of the *Legislation Act 2003*. The relevant instrument is freely accessible and free for use.

Item 2
This item repeals the heading of Division 1 of Part 5 and inserts a new heading, Division 1- Inspection fees.

Item 3
This item repeals section 53 of the Principal Regulation as, following the new fee structure for concurrent applications for licences, it is no longer necessary to have capacity to authorise 75% reduction in fees for concurrent applications.

Item 4

This item replaces, for the purposes of subsection 54(1), the current fee recoverable for an inspection of land or premises conducted in relation to an application for a licence, a permit that relates to the licence, a variation of a licence or a variation of a permit that relates to a licence with a flat fee of $3,650. The purpose of this pre-commissioning fee is to verify that the licence holder has implemented the correct physical infrastructure and security arrangements before any authorised activities might lawfully commence.

Item 5
This item replaces section 54B of the Principal Regulation; it prescribes, for the purposes of subparagraph 28(1)(e)(i) of the ND Act, that the charge payable to the Secretary on behalf of the Commonwealth on a licence is due and payable on the day specified in an invoice for the amount given to the licence holder by the Secretary.

Item 6
This item clarifies the effect of section 54C of the Principal Regulation to provide authority for the Secretary to, on behalf of the Commonwealth, recover (by action in a court of competent jurisdiction) 'an amount of charge' that is due and payable as a debt due to the Commonwealth.

Item 7
This item provides for the application provisions relating to the Regulations as follows:

(1) The repeal of section 53, and the amendment of Schedule 1, by the *Narcotic Drugs Amendment (Fees) Regulations 2020* apply in relation to applications made on or after 15 July 2020.

(2) The amendment of subsection 54(1) made by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to inspections started on or after 15 July 2020.

(3) The repeal and substitution of section 54B by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to charge on a licence in force on or after 15 July 2020.

(4) The amendment of section 54C by the *Narcotic Drugs Amendment (Fees) Regulations 2020* applies to charge on a licence in force on or after 15 July 2020.

Item 8
This item clarifies that Schedule 1 of the Regulations provides for application fees by replacing the current heading of the Schedule, 'fees' with 'Application fees'.

Item 9
This item amends the note to the heading to Schedule 1 and clarifies the authority for the application fees .

Item 10
This item repeals the table in clause 1 of Schedule 1 of the Regulations and replaces it with a new table that sets out application fees relating to cannabis licences and cannabis permits. 'Cannabis licence' and 'cannabis permit' are terms defined in the ND Act, and respectively include a medicinal cannabis licence and a cannabis research licence, and a medicinal cannabis permit and a cannabis research permit.

Items 4, 5, 6 and 7, give effect to the fee for an application for variation of a cannabis licence or a cannabis permit by way of an administrative instrument published on the Department of Health's website, defined in the Regulations as the variation application specification document. This is in accordance with the authority of subsection 28(2) of the ND Act which authorises the regulations to make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other document despite section 14 of the *Legislation Act 2003*. The relevant instrument is freely accessible and free for use.

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 2020

The *Narcotic Drugs Amendment (Fees) 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 27(1) of *Narcotic Drugs Act 1967* (the ND Act). The purpose of the Regulations is to amend the *Narcotic Drugs Regulation 2016* (the Principal Regulation) to provide for the restructure of certain fees related to applications for licences and permits.

The Regulations also provide for the adequate recovery of the costs for the work the Department of Health carries out in considering applications for licences and permits and in conducting related inspections. Specifically, for medicinal cannabis licences and cannabis research licences, the Regulations:

- Introduce a fee structure which reflects the number of *medicinal cannabis licence* and *cannabis research licence* applications submitted as follows:
    - single licence application;
    - *concurrent* applications for *two* licences at the same site;
- Reflecting its unnecessity following this new fee structure for concurrent applications for licences, the repeal of section 53 providing for 75% reduction for concurrent applications;
- Introduce a fee structure for applications to *vary* a *medicinal cannabis licence* or a *cannabis research licence* as follows:
    - *simple variation* – one example of which is to vary the licence to change the trading name of the licence holder;
    - *complex variation* – one example of which is to vary the licence to expand an existing licensed site or facility to include new cultivation or production areas or adding a new site or facility to an existing licence.

Note the means by which the variations are given effect is by way of the Regulations referencing an administrative instrument published on the Department of Health's website. This is in accordance with the authority of subsection 28(2) of the ND Act which authorises the regulations to make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other document despite section 14 of the *Legislation Act 2003*. The relevant instrument is freely accessible and free for use.

For medicinal cannabis permits and cannabis research permits, the Regulations introduce a fee structure for applications to *vary a permi*t as follows:

- *simple variation* – one example of which is an application to vary the permit to increase the maximum size of a cannabis crop *only* if that application does not require a variation to any other aspect of the permit;
- *complex variation* – one example of which is be an application to vary the permit to vary the types and strains of cannabis or cannabis plants that may be cultivated.

Note that because each permit requires separate consideration regardless of whether the application is concurrent with other permit applications there are no opportunities for efficiencies in effort by Department of Health officials when considering such concurrent applications. There is, therefore, no prescribed fee for processing concurrent applications for permits.

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