



**Australian Government**  
**Department of Health**  
Office of Drug Control

## Stakeholder Engagement Paper:

# Medicinal Cannabis Cost Recovery Framework

Consultation paper

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Version 1.0, March 2020

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## Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
10 March 2020	1.0	Original publication	ODC

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## Introduction

A comprehensive review of the Medicinal Cannabis Cost Recovery Framework was undertaken in late 2019 and early 2020. This paper presents the findings of that review, summarises the proposed changes and seeks further feedback from stakeholders. The outcome of this review will inform the Australian Government's consideration of the Medicinal Cannabis Cost Recovery Framework.

## Providing feedback

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 *Narcotic Drugs Act 1967* (the Act).

The ODC now invites formal feedback on the matters outlined in this paper. In particular, views are sought on the introduction of:

- the minor permit modification fee
- a licence charge
- a site charge
- follow up charges for audit, inspection and sampling
- investigation charges, and
- enforcement charges.

Feedback can be provided by completing the online consultation submission form to upload your feedback in either pdf or word format, or by submitting your feedback by email with the cover sheet to [mcs@health.gov.au](mailto:mcs@health.gov.au).

You are requested to provide any feedback to us by **20 March 2020**.

Feedback from this consultation process will be taken into account prior to final recommendations being made for consideration by Government to amend the Cost Recovery Framework.

## About this paper

This paper is limited in scope to the Act as it relates to medicinal cannabis and the Act as it is in force at the date of publication. It does not have any implications for manufacture licences granted for other narcotics.

Note that the Government has announced its intention to amend the Act to implement the recommendations from the 2019 Independent Review of the *Narcotic Drugs Act 1967*, and broader administrative reforms in the ODC. Following any future changes, the Cost Recovery Framework will be analysed to ensure it aligns to the reforms.

## Transition arrangements for the Single Licence Model

This paper is focussed on the existing legislative arrangements. However noting the recommendations from the 2019 Independent Review, you are invited to provide feedback on one issue relating to fees and the transition for existing licences to the single licence model

recommended in the 2019 review. Further consultation on the operational elements of the transition arrangements would be conducted at a later stage.

## Background

Australian Government policy is that it will charge the non-government sector some or all the efficient costs of specific government activities.<sup>1</sup>

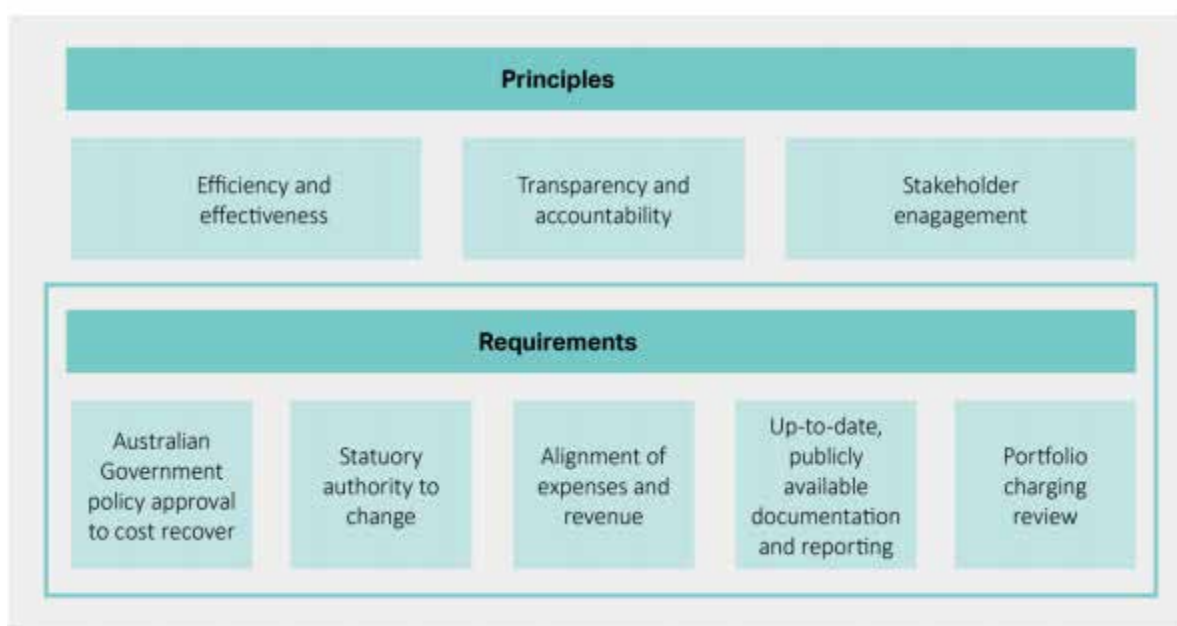
When establishing the Medicinal Cannabis Scheme in 2016, the Government determined that it was appropriate to charge both fees and levies to those interested in entering the Scheme.

The Australian Government Cost Recovery Guidelines (RMG304) outline the cost recovery principles the ODC must comply with when reviewing the fees and charges associated with the Scheme. The diagram below and the explanation that follows outlines these principles.

**Efficiency and Effectiveness** – proper use of resources to meet the policy outcomes including administration costs proportional to revenue and charges.

**Transparency and Accountability** – documentation of key information about the activity made available to all stakeholders (e.g. Cost Recovery Implementation Statement).

**Stakeholder engagement** – all affected stakeholders are consulted throughout the cost recovery process.



The costs of activities under the Act for medicinal cannabis are recovered through fees and a levy, known as the annual charge.

**Fees** are charged when a good, service or regulation is provided directly to a specific entity or organisation. Fees for applications or for inspections that relate to an application are applicable to the person who submits the application or requests an inspection. The Act provides authority to impose fees and the *Narcotic Drugs Regulation 2016* lists the price of those fees.

<sup>1</sup> Australian Government Cost Recovery Guidelines (RMG304)  
V1.0, March 2020

**Levies** are charged when a good, service or regulation is provided to a group of individuals or organisations. The annual charge, which all licence holders must pay, is a distribution of the costs of administering the Scheme, for example, the compliance monitoring costs. The *Narcotic Drugs (Licence Charges) Act 2016* provide authority to impose an annual charge and the *Narcotic Drugs (Licence Charges) Regulation 2016* lists the price of that charge.

**Funding** provided for the regulatory functions of the Medicinal Cannabis Scheme occurs through the Federal Budget. The fees and charges recovered from applicants and licence holders enters the Consolidated Revenue Fund. This is a different funding arrangement from that of the Therapeutic Goods Administration (TGA), which has a special account allowing the TGA to manage revenue collected through fees and charges under the *Therapeutic Goods Act 1989*.

The ODC receives annual appropriation funding that is determined by the forecasting of work volumes, which are documented in a Cost Recovery Implementation Statement which is published annually and updated as necessary.

Government processes are available to review funding where the funding previously provided is determined to be inadequate.

## Review of the Cost Recovery Framework

An activity based costing exercise was undertaken to document the tasks associated with the functions provided for in the Scheme, determining the average efficient time spent by a departmental employee on each task. This process included accounting for the time spent across tasks such as generating invoices, licence application assessments and compliance inspections.

The Department of Finance was consulted on proposed amendments to the Cost Recovery Framework and provided advice on the implementation of the proposed changes to fees and charges to comply with RMG304.

This has resulted in some changes to those raised in stakeholder engagement sessions, specifically with regard to the proposed charges.

## Findings of the review into the Cost Recovery Framework and Stakeholder Consultation Engagement Sessions

The findings consistently noted that:

- in order to adequately resource the ODC, and remove any cross subsidisation, the ODC should recover the costs of assessment and compliance activities associated with manufacture licences
- the current cost and structure of the fees and charges do not effectively recover the regulatory costs for the ODC to administer the Scheme
- the existing fee structure does not account for the effort to assess applications for complex and simple variations to licences
- cost of fees for multiple applications do not consider efficiencies obtained through simultaneous assessment of these applications (where appropriate)
- the average time from granting a licence to granting a permit is around two years as licence holders require time for complete construction of a site or facility

- the annual charge does not differentiate between a licence holder's compliance history, meaning those that are highly compliant pay the same charges as those who are non-compliant, despite non-compliance requiring greater effort by the ODC, and
- indexation of fees and charges should occur annually but has not been adjusted since introduction of the Medicinal Cannabis Scheme.

## Proposed amendments to the Cost Recovery Framework

A number of proposed amendments are being considered to the Cost Recovery Framework in response to the findings of the review. The proposed amendments fall broadly into four categories:

- extending cost recovery to medicinal cannabis manufacture licences
- amendments to fees
- amendments to the annual charge, and
- indexation of fees and charges.

[Appendix A](#) provides diagram of current fees and charges compared with proposed fees and charges.

### Extension of cost recovery to medicinal cannabis Manufacture licences

To date licence and permits for the manufacture of medicinal cannabis do not attract fees or charges. However, the review found that cost recovery of fees and charges should be extended to licences and permits issued for the manufacture of medicinal cannabis to ensure that the ODC receives adequate revenue to support the work it undertakes. This is also important to ensure that the administration of the Scheme aligns with the Australian Government Cost Recovery Guidelines.

The significance of this is that the overall cost of regulating the Medicinal Cannabis Scheme and the Act, recovered through fees and the annual charge, will be distributed more equally across the medicinal cannabis sector.

### Amendments to fees

The review found that the existing price of the fees does not adequately recover the costs for undertaking those activities. For most activities, the time required to complete the relevant tasks associated with the fees is significantly higher than what was forecast before the Medicinal Cannabis Scheme came into effect. [Appendix B](#) provides proposed costs for each fee.

#### *Introduce a fee structure that reflects the number of licence applications submitted*

The current fee structure only accounts for some efficiencies gained when concurrently assessing applications (e.g. a medicinal cannabis licence and cannabis research licence application submitted at the same time). Efficiencies will also be gained, should, as recommended, a fee for manufacture licences be introduced. Therefore, the following structure for licence application fees is proposed:

- application fee for a single licence application
- application for two licence applications, and
- application fee for three licence applications.



The fees are applicable only when submitting applications at the same time. Additional applications submitted at a different time will incur a single licence application fee.

#### *Introduce a new fee structure for applications to vary a licence*

The review determined that the effort required for the assessment of an application to vary a licence differs significantly, depending on the nature of the variation. Two variation types—simple and complex — were identified and an application fee is proposed for each type to reflect the effort involved.

*Simple variations* require less effort; the following are examples of simple variations:

- changing the period of the licence, or
- changing company trading name.

*Complex variations* require significantly more effort and are often similar to a new licence assessment in that they are a significant change to the operations of the licence holder.

The following variations are examples of complex variations:

- expanding an existing site or facility to include new cultivation, production or manufacture areas, or
- adding a new site or facility to a licence.

#### *Fees for permit variations*

The review identified that all non-minor variations to permits require a similar amount of effort to process, meaning that the review did not identify a need to classify different levels of effort when processing any permit variation applications, while noting the reference below to minor permit modifications.

Examples of permit variations that a licence holder may apply for include, but are not limited to:

- obtain new strains of cannabis
- increase the maximum quantity of cannabis plants that may be cultivated, cannabis or cannabis resin that may be produced, and/or
- add new supply pathways.

#### *Introduce a new fee – Minor permit modification*

The review identified that circumstances exist where a licence holder may seek to make a minor change to a permit which would not warrant a variation (i.e. change did not affect the total quantities of cannabis plants cultivated or cannabis or cannabis resin authorised under the permit). It is proposed that there is no application required however, a minor change to a permit still requires consideration by the ODC before they can be enacted.

When a licence holder notifies of their intention to make a minor modification to a permit a *Minor permit modification* fee is proposed, to recover costs associated with the administrative activities required to process the modification.

Examples of matters that may be subject to a minor permit modification fee, rather than a permit variation include, but are not limited to:

- rescheduling or rearranging the sequencing or cultivation crops without altering the agreed maximum quantities within any crop
- updating the permit anticipated volumes of cannabis waste based on actual data, or
- updating anticipated quantities of cannabis produced based on the actual data, including quantity of seeds produced from cross breeding events.

### **Amendments to the annual charge**

The most substantial changes proposed relate to the existing annual charge. In summary, it is proposed to divide the existing annual charge into two separate charges.

#### *Introduce an annual licence charge and an annual site charge*

The annual charge, paid by all licence holders, is the mechanism for recovering the costs of activities (performed by the ODC) which occur after a licence has been granted. The level of activity can vary depending on whether a licence holder is still undertaking construction of facilities or is operational under a permit. Where the licence holder is not operational, the ODC has a smaller compliance monitoring workload.

In accordance with the Australian Cost Recovery Guidelines, the licence holder cannot be charged for activities not undertaken. As a result, a new structure is proposed for the annual charge that divides the costs of administering the Scheme to licence holders who are in the construction phase (called the licence charge) and licence holders who have a site once it becomes operational (called the site charge).

*Licence charge* – would be incurred by all licence holders immediately after a licence is granted and each year thereafter. The charge includes the cost of the following activities:

- administrative operations of the ODC
- response to mandatory reporting by a licence holder (in accordance with the conditions of the licence, including those imposed by section 20 of the Narcotic Drugs Regulation 2016) relating to the licence holder, and
- inspections that are the result of a tip off.

*Site charge* – would be incurred by a licence holder, once a site has been inspected and a permit has been granted under the Act, and each year thereafter. The charge includes cost of the following activities:

- compliance monitoring inspection for the site or facility
- response to mandatory reporting by a licence holder (in accordance with the conditions of the licence, including those imposed by section 20 of the Narcotic Drugs Regulation 2016) of a complex nature, such as security incidents or loss or theft of cannabis
- sampling of cannabis during an inspection
- response to regular reports submitted by licence holders on activities that have occurred, and

- education and corrective action of licence holders.

*Appendix C provides the price of the proposed annual licence and site charges.*

*Note on licence holders with multiple sites*

It is proposed that a single site charge is applied to a licence holder even in circumstances where a licence holder has multiple sites authorised under their licence, since some efficiencies may be gained with such a licence holder. However, it is also proposed that, where required, additional compliance activities for a licence holder with multiple sites may fall under a separate amount payable for 'follow-up' activities.

### **Introduce new charges**

The review identified that developing a charging structure that reflects the compliance history of a licence holder would provide a more equitable approach as it places the extra costs on licensees requiring a higher level of monitoring, and provides an incentive to encourage compliance. As a result, three new categories of charges are proposed to avoid cross-subsidisation, where compliant licence holders contribute to payment of the costs of non-compliant licence holders.

All charges would be applied on an hourly basis, ensuring the cost of such activities will be commensurate to the severity of the non-compliance and the responsiveness of the licence holder in each scenario.

The intention for all new charges proposed below is the same, to directly recover the costs of addressing non-compliance with those responsible for the non-compliance. The proposed triggers for each charge are different and are described below.

[Appendix C](#) provides an indicative example of the potential costs of the proposed charges such activities could incur.

*Introduce new charges for follow up activities*

Some licence holders may, as a result of ongoing compliance and other circumstances, require multiple compliance monitoring inspections while others require a smaller number of inspections. The current annual charge only accounts for three compliance-monitoring inspections per licence holder.

Charges are proposed to be applied to the following activities:

- follow up audit charge –the cost of a desk top audit that may be triggered if an anomaly in record keeping is identified or the regularly reporting required of a licence holder
- follow up inspection charge –the cost of an inspection that may be triggered in the circumstances described above or history of non-compliance, and
- follow up sampling assessment charge –the cost of the assessment of the results of the analysis of a cannabis sample from a follow up inspection.

*Introduce new charges for investigation activities*

An investigation can be undertaken by an authorised person with the ODC in response to a breach of the Act that constitutes an offence or is subject to a civil penalty (refer to section 13M of the Act and Part 3 of the *Regulatory Powers (Standard Provisions) Act 2014*).

To date, costs for investigations have been recovered through the annual charge however it is more appropriate to recover these costs directly from the licence holder that is subject to the investigation. An investigation could be entirely undertaken from the ODC's office (e.g., desktop audit), or may require an inspection or sampling to be undertaken. Therefore, charges are proposed for the following activities:

- investigation charge – the costs of undertaking the investigations that are undertaken from the ODC's office
- investigation inspection charge – the costs associated with undertaking an inspection where investigation powers are used, and
- investigation sampling assessment charge – the cost of assessing the results of the analysis of a cannabis sample from an investigation inspection.

#### *Introduce new charges for enforcement activities*

An investigation may find that enforcement action is required to address a breach of the Act.

Enforcement charges are proposed to recover the cost of undertaking such enforcement action, with the costs to be recovered directly from the licence holder that is subject to the enforcement action. It is proposed that these costs would be in addition to any financial penalties that may be the result of enforcement action, such as a penalty payable pursuant to an infringement notice. Enforcement action charges are proposed for the following activities, which are indicative of the severity of the enforcement action.

- enforcement action: minor – this may relate to the cost of issuing an infringement notice or direction to a licence holder. It is the cost to the ODC of preparing to take this action. The cost to the licence holder of the amount payable pursuant to any infringement notice issued would be in addition to this charge
- enforcement action: moderate – this may relate to the cost to the ODC of preparing an enforceable undertaking or suspending a licence, and
- enforcement Action: major – this may relate to the cost to the ODC of preparing to issue an injunction or revoking a licence.

### **Indexation of fees and charges**

An annual indexation adjustment is recommended as part of the cost recovery framework. This will also ensure fees and charges are consistent with Government policy. The indexation model proposed is based on the approach taken by TGA, which has an indexation factor combining the wage price index (WPI) and the consumer price index (CPI) on a 50:50 basis.

### **Specific consideration of research licences**

The review into the Cost Recovery Framework did not identify any specific matters relating to research licences, however strong feedback was raised during the stakeholder sessions regarding the impact that fees and charges have on research, specifically research undertaken by non-commercial research bodies.

The Australian medicinal cannabis sector highly values research into medicinal cannabis and medicinal cannabis products, and the sector is of the view that the fees and charges for research licences should be sufficiently low to encourage and facilitate more research.

The current Cost Recovery Framework already provides for partial cost recovery regarding non-commercial research; however, it is proposed to review the risks associated with medicinal cannabis research licences and then undertake an activity based cost activity with consideration of these risks.

The assessment of the risks will have an impact on the work effort involved in assessing and monitoring research licences and permits and a consultation paper on medicinal cannabis research licences in the 2020-21 financial year, with the view to seek Government approval to implement any resulting changes soon thereafter.

## Transition arrangements for the single licence model

The 2019 Independent Review made 26 recommendations, with recommendation 7 being that a single licence model should be implemented under the Act. Although this paper concerns the Act in force at this time, you are invited to provide initial input on fees concerning transitional arrangements for a proposed single licence model.

In developing the transitional arrangements, one option under consideration is to legislatively deem an existing licence, or multiple licences held by the one entity, to constitute a single licence for the purposes of the Act. The single licence would take effect on the commencement day for the new legislative arrangements.

Under this model, it is proposed that existing licence holders would not need to formally apply for a new single licence.

Feedback is sought from existing licence holders on:

- their interest in having their licence documentation reviewed and if necessary reformatted in accordance with any new format or structure reflective of the new single licence arrangements, following the commencement of the new legislative arrangements, and
- paying a one-off administrative fee for review and reformat for a single licence that would be set in recognition that the level of work relates to existing licence holders and so would be less than the cost of the ODC assessing a new single licence application.

## Next steps

Government will determine whether the changes proposed in this paper are implemented and the date of commencement, possibly 1 July 2020. Following provision of consultation feedback to Government and subject to Government approval, amendments would be made to the legislative instruments that relate to Cost Recovery Framework, specifically the *Narcotic Drugs Regulation 2016* and the *Narcotic Drugs (Licence Charges) Regulation 2016*.

There would also be the requirement to publish the Medicinal Cannabis Cost Recovery Implementation Statement (CRIS). Prior to publication of the CRIS, a draft version of the document will be circulated for public comment.

## Appendix A: Diagram of current and proposed fees and charges

Current Fees/Charge	Proposed Fees/Charges			
Licence Application Fee	Single Licence Application Fee			
Discount Licence Application Fee	Double Licence Application Fee	Triple Licence Application Fee		
Licence Variation Fee	Licence Variation - Simple	Licence Variation - Complex		
Permit Application Fee	Permit Application Fee			
Permit Variation Fee	Permit Variation Fee	Minor Permit Modification Fee		
Inspection Fee	Pre-Commissioning Inspection Fee			
Annual Charge	Annual Licence Charge	Follow-up audit	Investigation	Enforcement Action – Minor
	Annual Site Charge	Follow-up Inspection	Investigation Inspection	Enforcement Action – Moderate
		Follow-up sampling assessment	Investigation sampling assessment	Enforcement Action – Major

## Appendix B: Proposed prices of amended fees and charges

The information outlined below is draft without prejudice. After receiving and consolidating feedback on this paper, the Department will seek formal approval to change the Cost Recovery Framework.

Fee	Current price	Current price Indexed to 2020-21**	Proposed Price 2020-21
Single Licence Application	\$5,040	\$5,440	\$8,080
Double Licence Application	\$6,300	\$6,800	\$8,710
Triple Licence Application	\$6,300	\$6,800	\$9,380
Permit Application	\$1,830	\$1,970	\$3,470
Licence Variation - Simple	\$3,900	\$4,210	\$1,100
Licence Variation - Complex	\$3,900	\$4,210	\$5,540
Permit Variation	\$1,730	\$1,870	\$2,920
Minor Permit Modification	-	-	\$120
Pre-Commissioning Inspection*	\$4,818	\$5,200	\$3,700

\*\* Price reflects what the fees and charges would have been had they been subject to an annual indexation to July 2020.

## Appendix C: Proposed prices of amended charges

The information outlined below is draft without prejudice. After receiving and consolidating feedback on this paper, the Department will seek formal approval to change the Cost Recovery Framework.

Charge	Current price	Current price Indexed to 2020-21**	Proposed Price 2020-21	Projected Unit cost 2020-21
Annual Licence Charge	\$27,380	\$29,540	\$11,750	-
Annual Site Charge	-	-	\$19,440	-
Follow-up audit*	-	-	-	\$3,138
Follow-up Inspection*	-	-	-	\$6,635
Follow-up sampling assessment*	-	-	-	\$1,219
Investigation*	-	-	-	\$8,932
Investigation inspection*	-	-	-	\$7,927
Investigation sampling assessment*	-	-	-	\$1,219
Enforcement Action: Minor*	-	-	-	\$4,462
Enforcement Action: Moderate*	-	-	-	\$5,176
Enforcement Action: Major*	-	-	-	\$7,045

\* Applied at an hourly rate – prices here are indicative only and will depend on the nature of the follow up activity or enforcement action.