Medicinal Cannabis Program Regulatory Fees and Charges Review

Consultation paper

December 2022

A close-up of a plant

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## About this Consultation Paper

This consultation paper is limited in scope to cost recovery for regulatory activities relating to **medicinal cannabis** undertaken under the *Narcotic Drugs Act 1967* (the Narcotic Drugs Act), as in force at the date of publication. It does not have any implications for regulatory activities relating to imports, exports, licences or permits granted for other narcotics.

On 24 December 2021 several changes to the Narcotic Drugs Act came into effect, including the introduction of a single licence model for cultivation, production and/or manufacture activities. At this time the Office of Drug Control (ODC) also implemented simpler permit processes and administrative reforms to reduce regulatory burden.

As part of these reforms, the existing cost model was also reviewed, including the level at which fees and charges were set. In doing so it became evident that some regulatory effort was not included in the existing fees and charges for the Medicinal Cannabis Program (the Program). A comprehensive review has now determined the minimum efficient costs of regulation and these costs have been reflected in the proposed new fees and charges set out below. It is proposed that the new schedule of fees and charges will commence on 1 July 2023.

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 costs to be recovered for the regulatory effort for the Program.

### Consultation Period

Industry consultation will have two elements to it, a consultation paper requesting feedback on proposed options and two public information webinars, where industry can receive further information on the proposed changes to the Program. Table 1 details the key dates within the consultation period.

Table 1: Key Consultation Dates

|  |  |
| --- | --- |
| **Action** | **Date** |
| Consultation Paper Published and consultation commences | 19 December 2022 |
| Closing date for consultation period and submissions | 10 February 2023 |

### How to Provide Feedback

The Consultation Paper has been structured in a manner to provide relevant information and seek feedback on the proposed fees and charges.

Feedback can be provided using the online submission form at [TGA / ODC Consultation Hub (tga.gov.au)](https://consultations.tga.gov.au/)  Alternately, submissions (in pdf or word format), along with the Consultation Submission Cover Sheet (at Attachment A), can be provided directly to the ODC via [mcs.application@health.gov.au](mailto:mcs.application@health.gov.au).

Submissions are due by **5pm on Friday 10 February 2023**.

## Policy Changes to the Medicinal Cannabis Program

The amendments to the Narcotic Drugs Act commenced on 24 December 2021. The main change for licences is to adopt a single licence model for medicinal cannabis regulation. In most cases the licence will also be perpetual, meaning it will be granted for an unlimited period (subject to surrender, suspension, or revocation in accordance with the Narcotic Drugs Act).

The amendments will support an innovative Australian medicinal cannabis industry for the benefit of Australian patients, reduce the regulatory burden and provide benefits to businesses.

Holders of multiple licences have now been transitioned to a single licence. New licences granted on and from the commencement date are single licences.

The amendments have also resulted in permits being simplified with a consistent format for each of the primary licence activities. Permits are now issued based on a ‘one permit, per activity, per site’ model, replacing the previous need for multiple permits to be concurrently held to undertake a particular activity such as cultivation. Permits are now issued for a 12-month period resulting in an “initial” permit application, followed by “subsequent” permit applications. The permit changes will also reduce the frequency that entities will need to apply for permit variations.

The existing 2021-22 fees and charges[[1]](#footnote-2) have remained applicable during a transitional period to allow for the comprehensive review of the cost recovery model and fees and charges, considering the revised legislative framework and in accordance with the Australian Government Charging Framework.

The [Cost Recovery Implementation Statement (CRIS)[[2]](#footnote-3)](https://www.odc.gov.au/sites/default/files/cris-regulation-of-medicinal-cannabis-2021-22.pdf) provides information on how the ODC currently implements cost recovery for regulatory activities associated with the Medicinal Cannabis Program under the Narcotic Drugs Act.

## The Australian Government Regulatory and Charging Policy

The Australian Government’s Regulator Performance Guide 2021 is an important part of its commitment to reduce unnecessary and inefficient regulation. The Regulatory Framework encourages regulators to minimise the regulatory burden created through regulatory administration.

The Australian Government Charging Framework[[3]](#footnote-4) (AGCF) sets the rules and requirements on how a regulator determines costs, set charges and how it will charge for regulatory activities. A key principle of the Government’s policy is that those who create the need for regulation should bear the cost of that regulatory effort. Prices for a regulatory activity are set to only recover the minimum efficient costs of carrying out that activity.

The AGCF uses three key charging mechanisms:

* Fee-For-Service – charges an individual or organisation for the delivery of regulatory activities, within the Program, these include licence and permit applications and variations to those applications.
* Cost Recovery Levy – charges a group of individuals or organisations for the delivery of regulatory services rather than to a specific individual or organisation. This includes all the support activities (e.g., helpdesk function, streamlined documentation, education, and compliance campaigns) conducted by the ODC that ensures they meet their policy and legislative responsibilities of delivering efficient regulation. A cost recovery levy is a tax and is imposed via a separate taxation Act. The cost recovery levy translates to the revised Annual Charge for all licence holders.
* Inspection Levy (e.g., Specific Cost Recovery Levy) – a charge that recovers the minimum efficient costs of regulatory inspections and verifications. This cost recovery charge is based on the regulatory cost associated with the administrating and conducting of inspections or verifications. It is proposed that the charge will be imposed at the point-in-time the inspection or verification occurs. The Inspection Levy translates to the revised Inspection Charge.

### Cost Model Review Findings and Revised Costing Approach

The Australian Government Cost Recovery Guidelines[[4]](#footnote-5) outline the cost recovery principles that the ODC must comply with when reviewing the fees and charges associated with regulatory activities. A review of the existing Medicinal Cannabis Program Activity Based Costing (ABC) Model (initially developed in 2016-17 and updated in 2020) was undertaken in 2022 to determine whether it was reflective of the new streamlined arrangements for the licensing and permits model. After a thorough assessment of the existing cost model and extensive consultations with subject matter experts within the ODC it was determined that the model no longer reflected the post reform activities and revised regulatory arrangements.

The existing cost model, which was seen as fit-for-purpose when it was developed, only recovered part of the full regulatory cost of these activities of the Program. The revised cost model is now more in line with the Charging Framework, as it includes all tasks associated with each regulatory activity, aligns with the reformed program structure and projects forward expenses and revenue over a four-year period.

Only the minimum efficient costs have been included in the revised fees and charges. Within the context of the AGCF, this means only the minimum costs necessary to provide the activity while still achieving policy and legislative requirements are to be included. Minimum efficient costs are usually divided into:

* Direct costs are those costs that can be directly attributed to the regulatory task and includes salaries and salary oncosts (e.g., training and superannuation), and supplier costs (e.g., office supplies and workers compensation premiums).
* Indirect costs are those costs that cannot be easily attributed to the regulatory task but are essential for regulation. Common indirect costs or overhead costs include salaries of staff in corporate areas (e.g., finance and/or human resources) and technical support (e.g., ITC and/or legal) areas, or accommodation costs (e.g., rent, maintenance, and utilities).

Further details on how the Program expenses have been costed is at Attachment B.

A key output of the current costing review was to cost the new regulatory activities that were not part of the old program structure. The costing review developed a comprehensive activity catalogue reflecting the seven broad activities of the Program. These activities were broken down into 88 specific outputs, made up of 593 individual regulatory tasks. The revised activity catalogue categorises these outputs according to their characteristics, for example: Fee-For-Service; Cost Recovery Levy; Monitoring Charges, and Non-Cost recoverable outputs. The cost recoverable outputs contain the post reform pricing points for the streamlined Medicinal Cannabis Program.

### Medicinal Cannabis Program Total Costs

The estimated cost for the Program in 2022-23 is $5.328m. This total cost can be broken down into $4.118m that can be cost recovered and $1.210m that is not cost recoverable.

The cost recoverable portion can be further broken down into:

* the delivery of licence and permit applications and variations, accounting for $1.191m of regulatory effort and will be recovered through Fee for Service fees.
* the delivery of regulatory support activities accounting for $2.523m of regulatory effort (e.g. enquiries management, industry education, regulatory governance, policy and procedure activities, IT and other corporate support services, investigation and enforcement, revocation and suspension) and is proposed to be recovered through the Annual Charge.
* the delivery of monitoring activities, accounting for $0.404m of regulatory effort and is proposed to be recovered through monitoring charges.

The non-recoverable activities are those activities that cannot be directly attributable to the regulation costs of Licence holders, this accounts for $1.210m of non-regulatory effort (e.g., advisory committees, developing regulatory policy options, and the review of the cost recovery model), these activities are funded by the Australian Government.

Table 2 provides the 2022-23 estimated expenses for the Program.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Table 2: Break Down of Recoverable Program Costs for 2022-23** | | | | | |
|  | **Recoverable** | | | **Non-Recoverable** | **Total Costs[[5]](#footnote-6)** |
| Fee For Service | CR Levy | Monitoring Charges | Appropriation |  |
| **Total Costs ($m)** | **$1.191** | **$2.523** | **$0.404** | **$1.210** | **$5.328** |

The recoverable and non-recoverable costs include all salaries, oncosts, supplier costs (based on 2022-23 estimated expenditure data) and other related program costs.

The AGCF identifies a range of activities generally undertaken by regulators that are non-recoverable, through a fee-for-service arrangement, including policy development; briefings, drafting of legislation; general advice to the government and Parliament and compliance and enforcement activities. Some of these activities may be recoverable under a cost recovery levy, if the costs of the activity, output or business process can be reasonably attributed to a leviable group of regulated organisations.

Where cost recovery is not appropriate, activities are identified as being Budget funded. Activities that are appropriate for Budget funding include work involving the Administrative Appeals Tribunal, some enforcement activities and Advisory Council meetings.

The Australian Government has decided that ‘non-commercial medicinal cannabis licences’, under which the activities will, or will primarily, be for medical or scientific research that is for a non-commercial purpose, will be partially cost-recovered.[[6]](#footnote-7) As such, the prices for these types of licences will not reflect the full cost of the ODC delivering these services. This recognises the Government’s commitment to research and innovation across Australian industries as a long-term driver of economic prosperity. There is no change proposed to this principle arising from the review of the cost model and the paper below notes the proposed changes to the annual charge for this category of licence.

**Program Funding Model**

The Australian Government has decided that the regulation of the program is to be cost recoverable, noting that under the AGCF some costs are not recoverable. It is estimated that approximately: $4.118m will be cost recovered through cost recovery fees and charges; and $1.210m is not cost recoverable and will be funded through government appropriation. The total proposed cost to administer the regulation for this program is therefore $5.328m. Figure 1 below provides high level examples of cost recoverable and non-cost recoverable activities.

**Figure 1: High-level funding pathways**

$5.328m annual Medicinal Cannabis program funding

Examples of activities delivered

Licence & Permit Applications

**Cost Recoverable**

Fee for service ($1.191m)

$4.118m revenue

Licence & Permit Variations

Enquiries Management

Industry Education

IT & other Corporate Services

Annual charge ($2.523m)

Regulatory Governance, Policy & Procedure activities

Investigation and Enforcement

Suspension and Revocation

Monitoring charges ($0.404m)

Verification Inspections

Routine ongoing Inspections

**Non-Cost Recoverable**

No charge applied ($1.210m)

Legislation Development

Secretariat

Application based inspections

Enabling Services

## Proposed Fees and Charges Approach

### Process used to amend Fees and Charges

The Program reforms have occurred in two-stages, with the review of fees and charges being the final stage. The ODC has undertaken a review of the current Program Activity Based Costing (ABC) Model developed in 2016/17, in line with its revised legislative responsibilities and the AGCF, which as noted above is a framework that government entities use to design, implement, and review regulatory charging activities.

A complete revision of all activities and tasks were undertaken and minimum staff effort was allocated to each task to determine the regulatory cost of each charge to industry. Volume data for the program was also used as an input in determining charges where relevant.

Based on this work a revised cost model was developed including a list of proposed fees and charges for all regulatory activities provided to industry.

Tables 3, 4 and 5 outlines the proposed charging structure for Licences, Permits, Inspections and the Annual Charge.

### Proposed Licence Fee Structure

The proposed structure for licence fees is detailed in Table 3. In summary, there has been a slight increase in the new licence application fee, which has not been updated since 2020. The cost model review also found that there was variable regulatory effort in licence variations. As such, and consistent with the streamlining principles of the reforms, it is proposed that four types of variation fees be established that group similar costs into each fee amount.

Table 3: Proposed Licence Fees Structure

|  |  |
| --- | --- |
| Proposed Licences Fees | Estimated Amount[[7]](#footnote-8) |
| **New Licence Application** | **$ 12,263** |
| **Licence Variation Type 1** | **$ 534 each** |
| - Change licence holder name  - Remove authorise persons from Licence |  |
| **Licence Variation Type 2** | **$ 1,357 each** |
| - Change period in which licence is in force  - Add new security measures  - Modify or Remove security measures  - Any other non-specified requirement |  |
| **Licence Variation Type 3** | **$ 1,981 each** |
| - Change of layout of site  - Change of floorplan of facility  - Add activity to Licence  - Add authorised person/s |  |
| **Licence Variation Type 4** | **$ 11,026 each** |
| - Add Additional Site |  |

### Proposed Permit Fee Structure

The proposed structure for permit fees is detailed in Table 4. The cost model review found that there was different regulatory effort associated with assessing initial and subsequent permit applications for both Cultivation and Production and for Manufacture permits, therefore separate fees are proposed. It was identified that not all regulatory costs had been included in previous permit application fees; hence the proposed approach reflects an increase in permit application fees. To limit the impact on industry an initial and subsequent application fee approach is proposed. There has been limited structural change to permit variations, however these fees have been structured to reflect the regulatory effort required to administer these variations, similar to the structure for licence variations.

Table 4: Proposed Permit Fees Structure

|  |  |
| --- | --- |
| Proposed Permit Fees | Estimated Amount3 |
| **Permit Application (Cultivation and Production) – Initial** | **$10,937** |
| **Permit Application (Cultivation and Production) – Subsequent** | **$8,375** |
| **Permit Application (Manufacturing) – Initial** | **$7,222** |
| **Permit Application (Manufacturing) - Subsequent** | **$5,526** |
| **Permit Variation Type 1** | **$ 570 each** |
| - Change to licence holder name  - Change to maximum quantity at any one time with no change to total quantity |  |
| **Permit Variation Type 2** | **$ 1,530 each** |
| * Change to supply pathways only |  |
| **Permit Variation Type 3** | **$ 4,743 each** |
| * Change to quantities or activities |  |

### Proposed Inspection and Annual Charge Structure

The proposed structure for inspections and annual charges is detailed in Table 5.

The Application Based Inspection[[8]](#footnote-9) remains and is now charged at $8,932 per inspection, compared to $3,670, which now reflects the regulatory effort in conducting application-based inspections. Routine/ongoing inspections and verification[[9]](#footnote-10) inspections are also based on the minimum efficient costs of conducting these inspections.

The site charge which was previously payable annually, and which included recovery of costs associated with routine compliance inspections, has now been removed. There will now be an inspection charge which will be payable when a licence holder is granted their first permit, then at any point when an ongoing or verification inspection is required, through a risk-based compliance approach[[10]](#footnote-11). The ongoing and verification inspection charges are significantly less than the previous site charge amount.

The Annual Charge will be determined by the number of licence holders, based at a point-in-time divided by the cost of all leviable activities that apply across all licence holders.

Partial cost-recovery of non-commercial medicinal cannabis licences under which the activities will, or will primarily, be for medical or scientific research that is for a non-commercial purpose, will be achieved by the holder of a non-commercial medicinal cannabis licences paying the Annual Charge only in the first year of the licence. (Noting this category of licence will not be perpetual but will be granted for a limited time dependant on the research undertaken). Non-commercial medicinal cannabis licences will be subject to the same inspection charges based on the risk-based compliance approach taken for all licence holders.

Table 5: Proposed Inspection and Annual Charge Structure

|  |  |
| --- | --- |
| Proposed Inspection and Annual Charges | Estimated Amount3 |
| **Application Based Inspection** | **$8,932** |
| **Routine/Ongoing Inspection** | **$12,064** |
| **Verification Inspection (typically conducted virtually)** | **$4,544** |
| **Annual Charge (based on 95 Licence holders)** | **$26,559** |
|  |  |

### The Program Indexation Strategy

Licence holders will see wholesale changes in fees and charges in 2023, reflecting the minimum efficient costs of regulatory activities identified by the Program’s comprehensive activity-based costing model. No indexation will be applied in this base year.

This Consultation Paper has identified three options in its approach to fees and charges, each of these have a different indexation strategy. Depending on which option Government agrees to will determine the indexation approach that will be used by the Program.

The preferred option is to increase or decrease fees and charges in-line with increased or decreased program costs, anticipating that there will only be minimal changes to fees and charges in future years (e.g., annual salary increases).

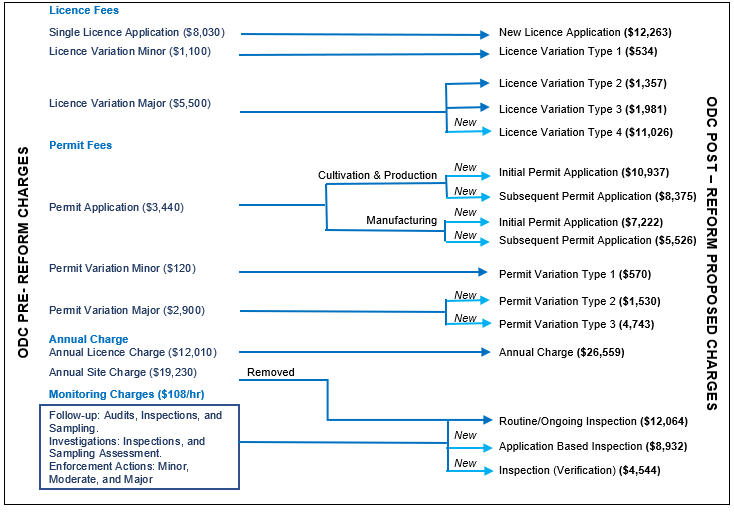
Ongoing monitoring and review of the cost model will identify any efficiencies with regulatory processes that could be passed on to industry. The review or indexation of the cost model in future years will be determined prior to the commencement of the year, following consultation.

Figure 2 below highlights the changes from current to proposed fees/charges and Figure 3 provides some examples to show the impact on licence and permit holders.

## Summary of Pre-Reform and Post Reform Pricing

Figure 2 shows the move from the pre reform pricing structure to the post reform pricing approach. The pricing structure has been developed around the key regulatory activities that the ODC has with licence holders. Prices have been determined by the regulatory effort incurred in delivering these activities to industry and only the minimum efficient costs of the regulatory effort have been included. To account for the range of regulatory effort in processing licence and permit variations, it is proposed to enhance the previous minor and major categories into variation types, where variations of similar regulatory effort are charged the same price.

**Figure 2: Pre and Post Reform Pricing Structure**



**Category Types**

**Licence Variation Type 1 (each):**

* Change licence holder business name
* Remove authorise persons from Licence

**Licence Variation Type 2 (each):**

* Change period in which licence is in force
* Add new security measures
* Modify or Remove security measures
* Other non-specified requirement

**Licence Variation Type 3 (each):**

* Change of layout of site
* Change of floorplan of facility
* Add Activity to Licence
* Add authorised person/s

**Licence Variation Type 4 (each):**

* Add Additional Site

**Permit Variation Type 1 (each):**

- Change to licence holder business name

- Change to maximum quantity at any one time with no change to total quantity

**Permit Variation Type 2 (each):**

* Change to supply pathways only

**Permit Variation Type 3 (each):**

* Change to quantities or activities

## Example Licence Holder Profiles – Estimated 2023 Charges

Figure 3 provides examples of the proposed new charges that will, as a minimum, apply in 2023-24 for six typical licence holder profiles.

**Figure 3: Examples of Licence Profiles**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 1. **Medicinal Cannabis Licence Program Entry – Initial licence application**   **Profile specific fees and charges proposed for 2023-24:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Licence application fee | $12,263 | | Annual licence charge | $26,559 | | **Total** | **$38,822** |   **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Licence application fee | $8,030 | | Annual licence charge | $12,010 | | **Total** | **$20,040** | | 1. **Existing Licence holder (with any or all authorised activities) - No permits**   **Profile specific fees and charges proposed for 2023-24:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $26,559 | | Licence variation fees | if required1 | | Initial permit application fee | if required2 | | Inspection charges | if required3 | | **Total** | **$26,559** |   1 If a licence variation application is submitted, a fee of $534, $1,357, $1,981, or $11,026 applies, depending on the variation type.  2 If an application for an initial permit is made, a fee of $10,937 or $7,222 would apply, depending on the activity type.  3 If an inspection is required, an application-based inspection amount of $8,932, or a routine/ongoing inspection amount of $12,064, or a verification inspection amount of $4,544 would apply, depending on the reason for inspection.  **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $12,010 | | Licence variation fees | if required4 | | Permit application fee | if required5 | | Inspection charge | if required6 | | **Total** | **$12,010** |   4 If a licence variation application is submitted, a fee of $5,500 for a major variation and $1,100 for a minor variation applies, depending on the variation type.  5 If an application for a permit is made, a fee of $3,440 would apply.  6 If an inspection is required, the applicable inspection amount is $3,670. |

**Figure 3: Examples of Licence Profiles (continued)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Existing Licence holder authorised for Cultivation, Production, and Manufacture activities – applied for an initial permit**   **Profile specific fees and charges proposed for 2023-24:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $26,559 | | Licence variation fee | if required1 | | Initial C&P permit  application fee | $10,937 | | Inspection | $8,9322 | | **Total** | **$46,428** |   1 If a licence variation application is submitted, a fee of $534, $1,357, $1,981, or $11,026 applies, depending on the variation type.  2 An initial site inspection to assist with the evaluation of the initial permit application is an application-based inspection, with an amount of $8,932.  **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $12,010 | | Permit application fee | $3,440 | | Licence variation fee | if required3 | | Inspection | $3,6704 | | **Total** | **$19,120** |   3 If a licence variation application is submitted, a fee of $5,500 for a major variation and $1,100 for a minor variation applies, depending on the variation type.  4 An inspection associated with the permit application applies. | 1. **Existing Licence holder authorised for Cultivation and Production (C&P) activities – with subsequent permit**   **Profile specific fees and charges proposed for 2023-24:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $26,559 | | Licence variation fees | if required1 | | Subsequent C&P permit  application fee | $8,375 | | Permit variation fees | if required2 | | Inspection | when required3 | | **Total** | **$34,934** |   1 If a licence variation application is submitted, a fee of $534, $1,357, $1,981, or $11,026 applies, depending on the variation type.  2 If a permit variation application is submitted, a fee of $570, or $1,530, or $4,743 would apply, depending on the type of variation.  3 When an inspection is required, an application-based inspection amount of $8,932, or a routine/ongoing inspection amount of $12,064, or a verification inspection amount of $4,544 would apply, depending on the reason for inspection.  **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $12,010 | | Annual site charge | $19,230 | | Licence variation fee | if required4 | | Permit application fee | $3,440 | | Permit variation fee | if required5 | | Inspection | when required6 | | **Total** | **$34,680** |   4 If a licence variation application is submitted, a fee of $5,500 for a major variation and $1,100 for a minor variation applies, depending on the variation type.  5 If a permit variation application is submitted, a fee of $120 for a minor variation and $2,900 for a major variation applies, depending on the variation type.  6 When an inspection is required, the applicable inspection amount is $3,670. |

**Figure 3: Examples of Licence Profiles (continued)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Existing Licence holder authorised for Manufacture (MAN) activities – with subsequent permit**   **Profile specific fees and charges proposed for 2023-24:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $26,559 | | Licence variation fees | if required1 | | Subsequent MAN permit  application fee | $5,526 | | Permit variation fees | if required2 | | Inspection | when required3 | | **Total** | **$32,085** |   1 If a licence variation application is submitted, a fee of $534, $1,357, $1,981, or $11,026 applies, depending on the variation type.  2 If a permit variation application is submitted, a fee of $570, or $1,530, or $4,743 would apply, depending on the type of variation.  3 When an inspection is required, an application-based inspection amount of $8,932, or a routine/ongoing inspection amount of $12,064, or a verification inspection amount of $4,544 would apply, depending on the reason for inspection.  **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $12,010 | | Annual site charge | $19,230 | | Licence variation | if required4 | | Permit application fee | $3,440 | | Permit variation fee | If required5 | | Inspection | when required6 | | **Total** | **$34,680** |   4 If a licence variation application is submitted, a fee of $5,500 for a major variation and $1,100 for a minor variation applies, depending on the variation type.  5 If a permit variation application is submitted, a fee of $120 for a minor variation and $2,900 for a major variation applies, depending on the variation type.  6 When an inspection is required, the applicable inspection amount is $3,670. | 1. **Existing Licence holder authorised for Cultivation, Production, and Manufacture activities – multiple sites – with permits**      |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $26,559 | | Licence variation fees | if required1 | | Subsequent C&P permit  application fee | 2 x $8,375 | | Subsequent MAN permit  application fee | $5,526 | | Permit variation fees | if required2 | | Inspection | when required3 | | **Total** | **$48,835** |   **Profile specific fees and charges proposed for 2023-24:**  1 If a licence variation application is submitted, a fee of $534, $1,357, $1,981, or $11,026 applies, depending on the variation type.  2 If a permit variation application is submitted, a fee of $570, or $1,530, or $4,743 would apply, depending on the type of variation.  3 When an inspection is required, an application-based inspection amount of $8,932, or a routine/ongoing inspection amount of $12,064, or a verification inspection amount of $4,544 would apply, depending on the reason for inspection.  **For comparison – fees and charges applicable to similar profile in 2022:**   |  |  | | --- | --- | | **Type of fee/charge** | **Baseline costs** | | Annual licence charge | $12,010 | | Licence variation fee | if required4 | | Annual site charge | $19,230 | | Permit application fee | 3 x $3,440 | | Permit variation fee | if required5 | | Inspection | if required6 | | **Total** | **$41,560** |   4 If a licence variation application is submitted, a fee of $1,100 or $5,500 would apply for a minor or major variation, respectively.  5 If a permit variation application is submitted, a fee of $120 or $2,900 would apply for the minor or major variation, respectively.  6 If an inspection is required, the applicable inspection fee is $3,670. |

## Proposed Options for Fee and Charges

Several options were considered prior to reaching a proposed approach. Options included:

**Option 1 – No Increase in fees and charges**

Not increasing fees and charges would result in under recovery of the full costs of regulatory activities, and therefore would be inconsistent with Government policy and the AGCF. Reduced revenues are likely to contribute to budget deficits, which will require ODC to reduce staffing and services to minimise this revenue impact. Reduced staffing will also extend application and permit timelines. In addition, this approach will most likely require a revised Government decision to freeze prices at the current level.

**Option 2 – Increase in-line with known increase in costs (proposed)**

The AGCF requires that fees and charges are set to reflect the minimum efficient cost of the regulatory task. This option is consistent with both the Government policy and the AGCF. Increases in fees and charges would be based on increases to minimum efficient costs. A reduction in expenses would also result in a reduction to fees and charges. Changes to fees and charges would occur on an annual basis, as necessary.

**Option 3 – Increase all Fees and Charges by an annual indexation amount**

Under this option fees and charges would be increased by a standard amount each year, for example, using CPI to increase fees and charges. A standard increase whilst efficient to administer, may not directly align to increases or decreases in Program expenses. This may result in either over or under recovery of the Program and could be inconsistent with the AGCF. In addition, this approach will most likely require a revised Government decision to set increases using the CPI.

## Proposed Implementation

Following consultation, the ODC will consider industry feedback and will provide a recommendation to the Minister for Health and Aged Care for a decision. The ODC will then progress relevant regulation amendments to implement the new fees and charges. The revised Program fees and charges will also be reflected in the Medicinal Cannabis Program Cost Recovery Implementation Statement (CRIS) and published on the ODC website. It is currently proposed the new charging arrangements will commence 1 July 2023.

## Attachment A: Consultation Submission Cover Sheet



ODC use only

*When* *completed this form will be classified as 'For official use only’*

Consultation Submission

This form accompanies a submission on the Medicinal Cannabis Program Regulatory Fees and Charges Review

|  |  |  |  |
| --- | --- | --- | --- |
| Name & work title |  | | |
| Company/Organisation |  | | |
| Company/Organisation address |  | | |
| Contact phone |  | Contact email: |  |

Publishing your submission

**Publish my entire submission in full**, including my name and work title as it appears on the submission, on the ODC website. **Note:** [Australian Privacy Principle 8.1](http://www.oaic.gov.au/agencies-and-organisations/app-guidelines/chapter-8-app-8-cross-border-disclosure-of-personal-information#overseas-recipient) will not apply if you consent to this.

Only **publish my submission** on the ODC website, **do not publish** my name or work title.

**Only publish** my name and work title on the ODC website, **do not publish** my submission.

**Do not publish** my name or work title **or** my submission on the ODC website.

**Only publish some** of my submission on the ODC website. I have:

Provided two copies - a complete submission that will not be published and a redacted submission which will be published. The redacted copy can be submitted with the parts of your submission that you **DO NOT** want published marked as ‘IN CONFIDENCE’

* + **OR** you may wish to apply track changes or blacked out text
  + **AND/OR provide details** of content not to be published in the box below. (e.g., “Do not publish pages 3-5”)

|  |
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Additional general information

Please provide the following general information to help with the analysis of stakeholder comments

|  |  |  |
| --- | --- | --- |
| I am, or I represent: | | |
| *Category* | | |
| Consumer | Consumer organisation | Government |
| Importer | Industry organisation | Institution  (e.g., hospital, university) |
| Laboratory professional | Manufacturer | Professional body |
| Regulatory affairs consultant | Researcher | Small business |
| Sole trader | Health professional (please specify): | |
| Other (please specify): | | |

We may contact you to ask you for more information or to seek feedback about how the consultation was undertaken. Please tick this box to consent.

\* The *Privacy Act 1988* contains 13 Australian Privacy Principles. Australian Privacy Principle 8.1 provides that:

Before an APP entity discloses personal information about an individual to a person (the overseas recipient):

1. who is not in Australia or an external Territory; and
2. who is not the entity or the individual;

the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach Australian Privacy Principles 2 - 13 in relation to the information. However, where a person consents to the publication of their personal information on the TGA Internet site or the Department of Health Internet site, APP 8.1 will no longer apply in relation to that publication.

For more information about the Australian Privacy Principles, visit the [Office of the Australian Information Commissioner’s website](http://www.oaic.gov.au).

For guidance on how your information will be treated by the Office of Drug Control see: Treatment of information provided to the ODC at [Privacy and personal information | Office of Drug Control (odc.gov.au)](https://www.odc.gov.au/privacy-and-personal-information).

## Attachment B: Development of the ODC Cost Model

The Activity Catalogue is the cornerstone to the revised cost model for the Program. Staff effort has been identified against 584 tasks. Staff effort has been validated and quality assured to ensure that only the minimum regulatory effort is recorded to deliver each task at the proficient officer level.

The Activity Based Cost (ABC) model includes direct costs (i.e., salary oncosts and supplier costs) and indirect costs (i.e., Overheads and ICT) and uses parameters derived from the Department of Finance new policy proposal template, to drive direct and indirect costs. Cost model assumptions provide context to the parameters and volumes. Figure 1 outlines the high-level cost model architecture.

**Figure 1: Draft Cost Model Architecture**

Stakeholder Engagement

Activity Catalogue

Staff Effort and Volumes

Direct Costs

Indirect Costs

Cost Base Database

Parameters and Assumptions

Revenue Model

Expense Model

Program Cost Model

**Staff Effort and Volumes:** Staff effort was determined for all tasks within the Activity Catalogue. Estimated volumes for the current year were also determined at the output level. Tasks were categorised as either volume driven or enduring. Regulatory and non-regulatory effort from operational staff was included in the costings where there was a direct line of sight between the task undertaken and the program deliverables (i.e., whole of program cost). Whilst some executive level officer effort was identified in the cost model, primarily reflecting responsibilities as a delegate of the Secretary, these were excluded based on simplicity and materiality.

**Cost Base Database:** Is the single source of ‘Truth’ for the program costs and relies on effort recording to derive effort across all staff. The cost base includes aggregation of both direct and indirect costs, an assessment against the Australian Government Charging Framework of which outputs are cost recoverable, and the proposed charging mechanism for the output.

**Parameters and Assumptions:** Includes allparameters including salary rates, oncosts metrics, suppliers and broader indirect attributions, and volumes. Assumptions are included to provide context to the parameters and could include broader program assumptions (e.g., expectations on the level of compliance by license holders, which would drive forecasted monitoring and compliance activity). Parameter and assumptions data combined with direct and indirect costs drives the expense and revenue results of the draft model.

**Expense Model:** Details all costs for the program (recoverable and non-recoverable), driven by effort, staff level, volume data and parameters. It includes the attribution of direct and indirect costs at the task level and includes capital costs where relevant. For multi-year cost models, the expense model also includes expense, volume, and revenue forecasts.

**Revenue Model:** Details the cost recoverable outputs, pricing points and the identified appropriate charging mechanism (e.g., Fee for Service, Broad based or Specific Output Levy) for each output. Based on volumes within the expense model, it drives unit price for all cost recoverable activities. For multi-year cost models, the revenue model also includes pricing options, indexation strategy, and potential charges for the out-years, and revenue forecasts.

1. The fees for the Program are set out in the Narcotic Drugs Regulation 2016 and the charges are set out in the Narcotic Drugs (Licences Charges) Regulation 2016. [↑](#footnote-ref-2)
2. The Regulation of Medicinal Cannabis 2021-22 is published at https://odc.gov.au [↑](#footnote-ref-3)
3. [Australian Government Charging Framework (RMG 302) | Department of Finance](https://www.finance.gov.au/government/managing-commonwealth-resources/managing-money-property/managing-money/australian-government-charging-framework) [↑](#footnote-ref-4)
4. [Australian Government Cost Recovery Guidelines (RMG 304) | Department of Finance](https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg-304) [↑](#footnote-ref-5)
5. Differences in Total Costs are caused by rounding. [↑](#footnote-ref-6)
6. See section 54A of the *Narcotic Drugs Regulation 2016*. [↑](#footnote-ref-7)
7. Proposed charges are estimated amounts and will be finalised in the published Cost Recovery Implementation Statement following industry consultation. [↑](#footnote-ref-8)
8. This activity was previously known as a Pre-Commissioning Inspection. [↑](#footnote-ref-9)
9. Verification inspections are either virtual or onsite inspections to verify veracity of information received or actions undertaken by the licence holder. [↑](#footnote-ref-10)
10. [Risk management approach to the cultivation, production and manufacture of medicinal cannabis | Office of Drug Control (odc.gov.au)](https://www.odc.gov.au/risk-management-approach-cultivation-production-and-manufacture-medicinal-cannabis) 2021. [↑](#footnote-ref-11)