Australian Government
Department of Health
Office of Drug Control

Cost Recovery Implementation Statement (CRIS)

Regulation of Medicinal Cannabis 2021-22

Effective from 01 July 2021

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Date	Version	Amendments	Approved by
January 2017	1.1	Updated to include reference of Narcotic Drugs (Licence Charges) Regulation 2016 and to align fees and licence charge to regulation	ODC
July 2018	1.2	Updated to include 2016-17 and 2017-18 actual financial results and non-financial information and reflect amendments in the Narcotic Drugs Regulation 2016 and Narcotic Drugs (Licence Charges) Regulation 2016	ODC
November 2018	1.3	Updated to reflect revised volume updates for future years and actual financial results for 2017-18	ODC
August 2021	1.4	Annual update of CRIS and application of indexation to fees and charges for the 2021-22 financial year	ODC
December 2021	1.5	Updated to reflect revised volume updates for future years and actual financial results for 2020-21	ODC

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1. Introduction

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a regulatory activity. This may include goods, services or regulation, or a combination of them. The Australian Government Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)[1], sets out the framework under which government entities design, implement and review regulatory charging activities, consistent with the *Public Governance, Performance and Accountability Act 2013*.

Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Australian Government Department of Health (the Department) implements cost recovery for regulatory activities associated with the Medicinal Cannabis Scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the Act).

This CRIS reports financial and non-financial performance information for the regulation of medicinal cannabis and contains financial forecasts for 2020-21, 2021-22 and three forward years. The Department will maintain the CRIS until the activity or cost recovery for the activity is discontinued.

Description of the regulatory charging activity

Australia is a party to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (the Single Convention). This convention aims to limit harm from illicit use or abuse of narcotic drugs while setting out the scope of permitted activities, such as for medical and/ or scientific use. The Single Convention imposes two key responsibilities on the Australian Government, as a party to the Single Convention. The first is an obligation to carefully control, supervise and report on cultivation, production, and manufacture of narcotic drugs, including medicinal cannabis. The second is to take measures to prevent the stockpiling or diversion of narcotic drugs, including medicinal cannabis, for illicit purposes.

The Act was enacted in 1967 to give effect to certain of Australia's obligations under the Single Convention. Significant amendments were made to the Act in 2016 to allow for the establishment of the Scheme and provide a pathway for lawful supply of medicinal cannabis to Australian patients. The amended Act was designed to ensure that Australia will remain compliant with its international treaty obligations in the Single Convention. In accordance with the Single Convention, the Office of Drug Control (ODC) within the Department, is the agency that has sole responsibility for the regulation of the cultivation and production of medicinal cannabis for medicinal and research purposes. No other Government agencies are involved in this partial cost recovery arrangement. The Department implemented and continues to administer the Scheme, which includes a licence and permit framework that allows for the cultivation, production, and manufacture of medicinal cannabis in Australia. The Scheme helps ensure Australian patients have access to essential medicine while supporting the Australian Government's policy of harm minimisation.

The *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* amends the Act to implement certain recommendations from the *Review of the Narcotic Drugs Act 1967* undertaken by Professor John McMillan AO in 2019 (further details are provided in Section 2). The amendments implement a single, perpetual licence model, replacing the current structure of requiring separate

[1] The Australian Government Charging Framework and the CRGs are available on the Department of Finance website (www.finance.gov.au).

medicinal cannabis licence for different activities. The amendments and relevant transitional provisions will commence on 24 December 2021, along with consequential regulation amendments.

In light of these legislative reforms, changes will also need to be made to the medicinal cannabis fees and charges framework. Cost recovery for the regulation of the Scheme aligns with the Government's overarching cost recovery policy which is, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of such activities. The cost recovery policy promotes consistent, transparent, and accountable charging for Government activities and supports the proper use of public resources. Fees and charges are imposed on applicants and licence holders who engage with the Scheme.

For the purposes of this document, the Scheme's cost recovery arrangements apply:

- for the period prior to 24 December 2021 to:
    - medicinal cannabis licences and permits
    - medicinal cannabis research licences and permits
    - medicinal cannabis-related manufacture licences and permits
    - compliance activities related to such licences and permits
- for the transitional period from 24 December 2021 until 30 June 2022 to:
    - medicinal cannabis licences, for any one or more of cultivation, production and manufacture activities
    - medicinal cannabis permits relating to cultivation and production activities
    - medicinal cannabis permits related manufacture activities, and
    - compliance activities related to such licence and permits.

Transitional period from 24 December 2021 to the end of the 2021-22 financial year

From 24 December 2021, where multiple licences have been converted into a single licence, transitional provisions operate to clarify the licence year anniversary date for the purposes of imposing annual charges. This is the earliest anniversary date out of the previously held licences, which occurs following the single licence transition on 24 December 2021. Licence charges will be invoiced annually by reference to this date going forward.

However, to prevent the possibility of a licence holder paying a site charge twice in the 2021-22 financial year due to these changes, an exemption from payment is made in the following circumstances:

- if the licence holder has a payable amount of site charge under a licence in force under the old framework between 1 July and 23 December 2021

  and

- the new licence year date for the converted single licence falls within the period 24 December 2021 and 30 June 2022 inclusive (the transitional period),

  then

- that licence holder does not have to pay any amount of site charge that would (but for this exception) have been due to be charged on the first new licence year date in the transitional period.

During the transitional period, a review of the cost recovery model and fees and charges will be conducted in accordance with the Australian Government Charging Framework and in consultation with stakeholders. Any resulting changes to fees and charges will commence on 1 July 2022, and a new CRIS reflecting both the new licence structure and associated cost recovery arrangements will be published at that time.

For further clarity, the following activities are not included in the cost recovery arrangements as they are conducted under separate legislation:

- costs for activities related to the import and export of medicinal cannabis under the Customs (Prohibited Imports) Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958
- costs for activities authorised under the *Therapeutic Goods Act 1989*, such as licences to manufacture therapeutic goods (Part 3-3) and costs for patient access to medicinal cannabis drugs through the Therapeutic Goods Administration's Authorised Prescriber process and Special Access Scheme.

Outline of the regulatory activities

Medicinal Cannabis Licences

From 24 December 2021, an applicant may make an application for a licence for regulating any one or more of medicinal cannabis cultivation, production or manufacture activities. The Secretary of the Department of Health (the Secretary) or a Delegate of the Secretary (a Delegate) must make a decision on that application. In making a decision, the Delegate must be reasonably satisfied with the following factors.

- The applicant and the applicant's relevant business associates must be considered fit and proper persons to either hold a licence or be associated with a licence. This involves consideration of a range of matters including criminal history, connections, associates and family, financial status, business history and capacity to comply with licensing requirements. Licence holders are to remain 'fit and proper' for the duration of the licence. This test is explicitly designed to ensure the exclusion of persons who may be tempted to use the Scheme as cover for illegal activities.
- For a medicinal cannabis licence, it must be established that a legitimate supply arrangement exists between the applicant and the holder of a licence to produce or manufacture medicinal cannabis. This is to prevent the diversion of cannabis and to ensure that the activities are related to the medicinal use of cannabis.
- It must be established that the applicant has the ability to maintain the physical security of the cannabis plants, cannabis or cannabis resin and/or medicinal cannabis drug.

Medicinal Cannabis Permits

Once a licence is granted, a licence holder must undertake the activities authorised under the licence in accordance with one or more permits. A licence holder must submit a permit

application and a Delegate must make a decision on that application. In deciding to grant a permit, the Delegate will set limits on the scope of the activities that can be undertaken, such as:

- the quantity of cannabis plants can be cultivated
- the quantity of cannabis and/or cannabis resins can be produced
- the maximum quantity of the drug that may be manufactured.

Cannabis permits are only granted for production where there is a contract between the licence holder and an authorised producer or licensed manufacturer. This assists in meeting a key obligation of the Single Convention to prevent over-production and diversion to illicit uses.

Compliance and enforcement

Cannabis licences are subject to statutory conditions and a Delegate can impose conditions on the licence to promote security of the crop, cannabis, and cannabis resins, so that it is not diverted to illicit uses. Substantial penalties exist for contravention of these conditions and offences relating to activities that are not authorised by the cultivation or production licence.

2. Policy and statutory authority to cost recover

Government policy authority

In the 2015-16 Mid-Year Economic and Fiscal Outlook, the Government announced its intention to establish a Commonwealth licensing scheme, to be administered by the Department[2], to regulate the cultivation of cannabis for medicinal and scientific use.

Additionally, in the 2016-17 Budget, the Government announced that it would introduce legislation to allow charges to be imposed on cannabis-related licences granted under the Act. Any revenue collected will support the Scheme for the regulation of cannabis for medicinal and scientific use.

Given the greater than anticipated interest in the Scheme, in the 2018-19 Mid-Year Economic and Fiscal Outlook, the Government increased resourcing to administer the Scheme and required the Department to review the cost recovery arrangements[3]. As a result of the review, the Department developed a proposal for amendments to fees and charges for the Scheme and undertook a detailed program of stakeholder engagement.

In the 2020-21 Budget, the Government announced the extension of cost recovery arrangements to medicinal cannabis-related manufacture licences and increased resourcing to meet the ongoing demands of administering the Scheme. Changes to fees and charges were outlined that commenced on 1 November 2020.

There are no changes to the partial cost recovery arrangements that relate to non-commercial cannabis research licences or for non-commercial cannabis-related manufacture licences. It was determined that full recovery may reduce investment in research. The shortfall in costs will continue to be met through appropriation from the Australian Government.

[2] Mid-Year Economic and Fiscal Outlook 2015-16, https://archive.budget.gov.au/2015-16/myefo/MYEFO_2015-16_Final.pdf, p.180.
[3] Mid-Year Economic and Fiscal Outlook2018-19, https://archive.budget.gov.au/2018-19/myefo/myefo_2018-19.pdf, p.189.

Statutory authority to charge

The Act[4] allows for regulations that provide for the imposition of fees for any matters within it, including matters relating to the payment of fees and charges. The Narcotic Drugs Regulation 2016 (the Narcotic Drugs Regulation) is the instrument that specifies the fees related to applications and inspections.

The *Narcotic Drugs (Licence Charges) Act 2016* (the Licence Charges Act) provides authority to impose a charge on a licence granted under the Act and that is in force within a specified period. These charges assist the Commonwealth in recovering the costs of the administration, monitoring and assessment of compliance with the requirements under the Act. Section 8 of the Licence Charges Act allows regulations to prescribe amount of charges.

The Narcotic Drugs (Licence Charges) Regulation 2016 (the Licence Charges Regulation) specifies the period the charge is imposed, the amount and how the charge is calculated. It also provides for non-commercial medicinal cannabis licence holders to pay one licence charge for the period for which the licence is in force, instead of for each 12-month period that the licence is in force. A non-commercial medicinal cannabis licence is defined in section 54A of the Narcotic Drugs Regulation. Non-commercial medicinal cannabis licences will not be perpetual but will be issued for a specified time period related to the research to be undertaken.

Statutory Review of the Narcotic Drugs Act 1967

In 2018, in accordance with section 26A of the Act, the Hon Greg Hunt MP appointed Professor John McMillan AO to conduct a review and provide a report on the operation of the Act. The Report on the Review of the *Narcotic Drugs Act 1967* (the Report) was tabled in Parliament in September 2019.

The Report made 26 recommendations to improve the regulatory framework for the cultivation, production, and manufacture of medicinal cannabis in Australia, which were accepted by Minister Hunt. The recommendations broadly aim to reduce the regulatory burden on the medicinal cannabis sector as well as to promote and allow greater flexibility in the administration of the legislation to support innovation and development.

A two-stage reform process was undertaken to ensure that the recommendations were appropriately implemented. Stage 1 involved making amendments to the Narcotic Drugs Regulation to streamline the application process, which were implemented on 1 January 2020.

Stage 2 involved amending the Act to implement certain recommendations from the Report. The *Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021* (the Amendment Act) received Royal Assent on 24 June 2021 amending the Act to provide a single licence framework to reduce the burden of regulation in the licence assessment process, provide greater certainty to business and reduce duplicative processes. The amendments and relevant transitional provisions will commence on 24 December 2021, along with consequential regulation amendments.

[4] *Narcotic Drugs Act 1967*, Section 28 (1)(c), (d) and (e).

3. Cost recovery model

3.1 Outputs and business processes of the regulatory activity

Outputs

The Scheme has the following key outputs for which costs are recovered:

1. applications for license and permits
2. inspections
3. activities covered by annual licence charge
4. activities covered by annual site charge
5. non-compliance follow ups

Business processes to deliver key outputs

The business processes below allow similar business processes to be categorised together. However, the mechanism for recovering the costs of these processes differs depending on the context in which the business process occurs.

3.1.1 Output 1 - Applications

The Scheme allows for a number of different applications that have similar processes, however the effort and time required for each process varies depending on the nature of the application.

The process related to an application is as follows:

- receipting - which includes filing all documentation and handling payment of invoices
- qualitative screening of the applications
- assessment of the application
- decision by a delegate to grant or refuse to grant a medicinal cannabis licence, permit, or variation to a medicinal cannabis licence or permit
- notification of decision made.

Application for a medicinal cannabis licence

Any person interested in undertaking cultivation, production, or cannabis–related manufacture under the Scheme must apply for a medicinal cannabis licence and a Delegate must make a decision on the application. While each medicinal cannabis licence application considers different information that reflects the nature of the activity to be authorised, the Department's internal cost recovery review found that the average efficient time for assessing each medicinal cannabis licence type was comparable.

The assessment of a medicinal cannabis licence application includes consideration of the applicant as a fit and proper person to hold a licence, the ability of the applicant to maintain security of the cannabis, cannabis resin or cannabis drugs and alignment of the proposed activities with Australia's obligations under the Single Convention.

Application to vary a medicinal cannabis licence

A licence holder can apply to vary a medicinal cannabis licence. The effort required for the handling of such an application differs significantly, depending on the nature of the variation. As a result, the application fee to vary a medicinal cannabis licence is divided into two categories:

- application to vary a medicinal cannabis licence – simple/minor
- application to vary a medicinal cannabis licence – complex/major.[5]

Application for a medicinal cannabis permit

Any activities authorised under a medicinal cannabis licence must be undertaken in compliance with a valid cannabis permit. As such, once a medicinal cannabis licence is granted, a licence holder may apply for one or more cannabis related permits.

Medicinal cannabis permits are used to control the quantities of cannabis plants cultivated, cannabis or cannabis resin produced and quantities of cannabis drugs that are manufactured. A medicinal cannabis permit is a critical tool in ensuring Australia complies with its international obligations under the Single Convention. The assessment of a medicinal cannabis permit will verify that the source/s of the cannabis plants, cannabis or cannabis resin are licit and require evidence of contracts between entities that are supplying or receiving cannabis plant, cannabis, or cannabis resin.

Applications to vary a medicinal cannabis permit

As with a medicinal cannabis licence, a licence holder can apply to vary a medicinal cannabis permit and the effort associated with handling that application differs significantly on the nature of the variation. Similarly, the application fee to vary a medicinal cannabis permit is divided into two categories:

- application to vary a medicinal cannabis permit – simple/minor
- application to vary a medicinal cannabis permit – complex/major.

3.1.2 Output 2 - Inspections

An inspection is undertaken to verify matters relating to medicinal cannabis licences or permits. It is Departmental policy that two Authorised Inspectors attend all inspections given the potential seriousness of the non-compliance and all charges are indicative of this effort. The manner in which the costs of inspections are recovered varies depending on the context of the inspection and effort undertaken.

[5] Prior to 24 December 2021, the two variation categories for licences and permits were simple/complex. Following the single licence related regulation amendments, these were renamed and are now called minor/major variations.

The following activities are associated with all inspections:

- plan and book
- travel
- conduct inspection
- finalise inspection
- notification and follow up.

Planned Inspection

Upon the granting of a medicinal cannabis licence and prior to the granting of a cannabis permit, the Department will conduct a planned inspection of the premises to ensure that the site is compliant with the conditions of the medicinal cannabis licence and is in accordance with the proposed site/facility plans provided with the application. It is a pre-requisite for a medicinal cannabis permit application that a planned inspection of the site has been conducted.

Historical data has demonstrated that all planned (pre-permit) inspections occur within a similar timeframe and are shorter in duration compared to subsequent compliance monitoring inspections as there are usually no cannabis plants, cannabis or cannabis resin on site at the time of the pre-permit inspection.

Compliance monitoring inspections

Every licence holder is subject to an annual compliance monitoring inspection whereby Authorised Inspectors undertake an inspection using monitoring powers as outlined under Division 2, Subdivision A of the *Regulatory Powers (Standard Provisions) Act 2014* (the Regulatory Powers Act). Associated costs are included in the 'Annual Site Levy'.

Public concern (tip off) inspections

This is a compliance monitoring inspection as described above, however is in response to a tip off or complaint from the public.

Follow up inspections

This is a compliance monitoring inspection as described above however it is undertaken in response to suspected non-compliance by a licence holder. The associated costs are categorised as 'non-compliance follow up charges'.

Investigation inspection

Authorised Inspectors can undertake an inspection using investigation powers as outlined in Part 3, Division 1 of the Regulatory Powers Act as the result of identified non-compliance. The associated costs are categorised as 'non-compliance follow up charges'.

Inspection related travel costs

Inspection related travel costs include accommodation, airfares, train fares, car hire, taxi or other car services, tolls, meals, or other allowances for departmental employees, and whole of government booking fees. The actual travel costs depend on the geographical location, with licensed sites in all states and territories and some within regional and remote areas. In keeping with Cost Recovery Guideline principles, costs for inspection related travel will be recovered in different ways, depending on the type of inspection.

Planned inspections: Applicants will not pay any inspection related travel costs for planned inspections. The Department has been provided appropriated funding for this cost, to remove any financial disadvantage for potential licence or permit holders in rural or remote locations who would be subject to higher travel costs based on their location.

Compliance monitoring and public concern (tip off) inspections: The travel costs for inspections will be rationalised across the industry and recovered through the annual licence and site charges.

Follow up and investigation inspections: The department will seek reimbursement of all reasonable domestic travel costs from licence holders that are subject to inspections. The licence holder will be provided with an invoice for the costs of all reasonable travel expenses. This ensures that those responsible for non-compliant behaviour pay for the costs incurred by the Department in managing the issues. It removes any cross subsidisation of such costs by compliant licence holders.

Testing of cannabis samples

During an inspection, an Authorised Inspector has the power to gather samples of cannabis or cannabis resin and take that sample for testing. Samples are tested at the Therapeutic Goods Administration (TGA) to determine the cannabinoid content of the cannabis and verify if the test results comply with the cannabinoid content listed on the relevant cannabis permit. The costs of undertaking these tests is $1,230 and this is passed directly to the licence holder.

3.1.3 Output 3 – Annual licence charge

Annual licence charge

An annual licence charge covers the costs of the following activities:

- response to mandatory notification
- public concern (tip off) inspections – refer to section 3.1.2
- continuous improvement.

Response to mandatory notification

In accordance with section 20 of the Narcotic Drugs Regulation, it is a condition that all licence holders notify a Delegate of certain matters. As the Department must respond to these notifications, the cost of such responses is included in charges to licence holders. Not all matters relate to non-compliance. However, the Department must review each matter and respond accordingly.

Some of the matters that a licence holder must notify a Delegate of relate to the loss or theft of cannabis plants, cannabis, or cannabis resin. Other matters relate to the licence holder itself, such as notification of new shareholders and business associates. As a result, the recovery of costs associated with a response to mandatory reporting is divided between the annual charge and the site charge, recognising that a certain volume of effort is only required once a cannabis permit is granted.

The following activities are associated with a response to mandatory notification:

- receive and register the notification
- review and analyse the notification
- make a determination on the matter
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

Continuous improvement

To ensure that the Department remains an agile and responsive regulator, the costs of undertaking continuous improvement of the Scheme by the Department has been incorporated into the cost recovery arrangements.

The following activities are associated with this business process:

- legislative reform and the associated processes
- development and maintenance of publicly available guidance
- stakeholder engagement activities
- activity based costing processes and ongoing management of the cost recovery arrangements.

3.1.4 Output 4 – Annual site charge

Annual site charge

In addition to the annual licence charge, if one or more permits are granted to a licence holder, an annual site charge will be incurred that covers the costs of the following activities:

- compliance monitoring inspection – refer to section 3.1.2
- cannabis permit reporting
- education and corrective action
- response to mandatory notification – refer to section 3.1.3.

Review of mandatory cannabis permit reporting

Once a cannabis permit is granted, permit holders are obliged to provide reports on their activities in accordance with that cannabis permit. The Department will assess these reports on a quarterly basis as follows:

- receive and register reports
- review and analyse the report/s
- make determination on matter
- where relevant, refer matter of potential non-compliance to the relevant team for action
- notify licence holder of outcome.

Education and corrective action

As the result of an inspection, desktop audit, cannabis permit report or a follow up audit, the Department may identify actions or behaviours on the part of a licence holder that, while not a matter of non-compliance, raises some concerns. In these instances, the Department may elect to undertake an educative approach with the licence holder or seek that the licence holders take corrective actions.

The following activities are associated with this business process:

- receive and review matter
- liaise with licence holder
- where relevant, provide documentation outlining corrective action to licence holder
- reconcile evidence that corrective action has been undertaken
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

3.1.5 Output 5 – Non-compliance follow up

Follow up desktop auditing

Where the Department identifies potential non-compliance, either as the result of an inspection, a tip off from the public, or the analysis of a cannabis permit report, they may elect to undertake a desktop audit to gather further information. For example, the Department may request that a licence holder provide all records related to the harvest of a specific crop to audit, in the office. Any findings of concern may be referred for an investigation.

The following activities are associated with this business process:

- receive and review matter
- document facts and assess risk
- develop audit plan
- gather documentary evidence
- analyse data and complete report
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome.

Investigations

While inspections and testing of cannabis samples are related to investigations, a significant amount of this work is undertaken within the office.

The following activities are associated with the in-office component of an inspection:

- receive and review matter
- document facts and assess risk
- develop investigation plan
- gather documentary evidence
- prepare brief of evidence
- finalise report.

Enforcement action

In the circumstances where non-compliance with a medicinal cannabis licence or permit or an offence against the Act has been confirmed, a number of enforcement actions are available to the Department. The enforcement action available is outlined in the Act, through reference to the Regulatory Powers Act.

While the specific enforcement action ranges in severity, and the effort required to prepare for such action differs, the activities associated with such business activities are similar, as described below:

- receive and review matter
- assess the non-compliance and information available
- review compliance history
- decision
- notification.

The enforcement actions are separated into minor, moderate and major to reflect the significance of the effort involved in preparing and undertaking the enforcement action. The charges associated with enforcement action are separate to any financial penalties that may result from the enforcement action.

Minor enforcement action: This category of charge relates to the preparation of an infringement notice given to a licence holder in accordance with Part 5, Division 2 of the Regulatory Powers Act. Further, it includes the preparatory effort associated with a Secretary's own variation of a medicinal cannabis licence or permit which may result from a matter of non-compliance or in issuing a direction to a licence holder under Part 3 of the Act.

Moderate enforcement action: This category of charge relates to the effort required by the Department to prepare for an enforceable undertaking in accordance with Part 6 of the Regulatory Powers Act or suspending a medicinal cannabis licence or permit as provided for in section 11A of the Act.

Major enforcement action: This category of charge relates to the effort required by the Department to prepare for an injunction in accordance with Part 7 of the Regulatory Powers Act or the revocation of a medicinal cannabis licence or permit as provided for in section 10P of the Act.

3.2 Costs of the regulatory charging activity

Activity Based Costing

An activity-based costing exercise was undertaken to determine the average efficient time spent by a departmental employee on each task. This process included accounting for the time spent across tasks such as medicinal cannabis licence and permit application assessments and compliance inspections. This allowed the Department to determine the direct and indirect costs of regulating the Scheme. Some indirect costs, such as the Secretariat function for the Australian Advisory Council on the Medicinal Use of Cannabis, have not been included within the cost recovery arrangements and alternative funding arrangements have been sought for this activity.

Fees and charges are indexed annually to reflect the efficient costs of providing the services and undertaking the activities required to regulate the medicinal cannabis industry.

Tables 1 and 2 summarise the direct and indirect costs of each fee and charge for the 2021-22 financial year.

Cost drivers and assumptions

In determining the cost drivers, a number of assumptions were made based on historical data and experience from undertaking such activities. The Department analysed the trends in volumes of applications received, time taken to undertake specific activities and the behaviours of the medicinal cannabis sector in predicting future volumes. For example, the Department determined the average time from the point at which a medicinal cannabis licence is granted to the point when a licenced site is completed, and a cannabis permit granted is approximately 2 years. This period was factored into the future volumes of cannabis permit applications and planned inspections, as well as explaining the separation of the annual charge into a licence and site charge.

These estimates are highly sensitive to the growth of both the domestic and global medicinal cannabis markets, which are limited by the requirements of the Single Convention and regulated by the International Narcotics Control Board (INCB).

Table 1: Estimated costs for fees and charges title

Estimated costs	Direct costs	Indirect costs	Total costs
Output 1 - Applications			
Application for a cannabis licence (Single)	$6,447	$1,581	$8,028
Applications for two cannabis licences (Double)*	$6,942	$1,704	$8,646
Applications for three cannabis licences (Triple)*	$7,482	$1,837	$9,319
Application to vary a cannabis licence – simple	$865	$234	$1,099
Application to vary a cannabis licence – complex	$4,438	$1,065	$5,503
Application for a cannabis permit	$2,788	$653	$3,441

Estimated costs	Direct costs	Indirect costs	Total costs
Application to vary a cannabis permit – simple	$96	$27	$123
Application to vary a cannabis permit – complex	$2,349	$547	$2,896
Output 2 – Planned Inspection	$2,927	$741	$3,668
Output 3 - Annual licence charge	$9,712	$2,295	$12,007
Output 4 – Annual site charge	$16,131	$3,102	$19,233

***Fee applicable prior to 24 December 2021 only**

3.3 Design of regulatory charges

Australian Government policy is that it will charge the non-government sector some or all the efficient costs of specific government activities. The characteristics of a government activity determine the type of cost recovery charge used.

Fees

The Department uses fees to recover costs when services are provided directly to an individual applicant or licence holder. A fee is applicable where the activity is driven by an action of the applicant or licence holder.

All applications are subject to an application fee, to be paid by the applicant and all planned inspections, which relate to an application, are also subject to a fee. These services are in direct response to a request from an individual or organisation.

Charges (Levies)

The costs of activities relating to the monitoring or response to potential or actual non-compliance of a licence holder are recovered using charges. Charges, also referred to as levies, legally are taxation charges. However, they differ to general taxation in that the costs recovered are earmarked to fund activities directly related to the Scheme.

The annual charges (levies) are associated with costs which are not driven by the actions of individual persons or entities but pertain to the industry as a whole or to an identifiable sub-set of the industry. The activity is driven by the government as part of its regulation of the industry. A charge is levied to all entities in the particular sector.

There are different activities undertaken by the Department for the regulation of medicinal cannabis licences and for the regulation of sites as outlined above at 3.1.3 and 3.1.4.

Under the Cost Recovery Guidelines there should be no cross-subsidisation of one identifiable group of entities by another. For this reason, the annual levies have been divided into an annual licence charge (charged once annually to each licensee per licence) and an annual site charge which is charged annually where a licence has an associated permit.

For non-commercial medicinal cannabis licences full cost recovery may stifle scientific innovation and the development of the medicinal cannabis industry in Australia. These non-commercial

medicinal cannabis licence holders are subject to both a licence charge incurred following the grant of a licence and a site charge incurred following the grant of a permit.

To provide reduced regulatory costs, non-commercial medicinal cannabis licence holders are only required to pay each of these charges once during the period of the licence, compared with the requirement for commercial licence holders to pay these charges annually. The shortfall in revenue for each non-commercial medicinal cannabis licence is met by appropriation funding from government.

Charges which can be identified with individual entities are the recovery of costs associated with non-compliance. These are determined on an hourly basis for associated staff time, plus costs as outlined in Table 2.

Table 2: Indicative costs for non-compliance follow up (Output 5)

Indicative costs	Direct Costs	Indirect costs	Total costs
Follow up desk top auditing	$2,538	$585	$3123
Follow up inspection	$5,727	$899	$6,626
Investigation	$7,122	$1,738	$8,860
Investigation inspection	$6,766	$1,143	$7,909
Enforcement action – minor	$3,660	$782	$4,442
Enforcement action – moderate	$4,256	$897	$5,153
Enforcement action - major	$5,796	$1,218	$7,014

Fees and charges – effective 1 July 2021

The fees and charges payable in the 2021-22 financial year and the estimated revenue for this financial year are listed in Tables 3 and 4. The proposed increase to the fees and charges is based on an indexation formula used to calculate adjustments to fees and charges based on the relevant work effort, and average salary rates for the Department of Health.

As a result of the indexation, the inspection fee increased by approximately 0.5% and the application fees increased by approximately 0.9%. In applying this increase, the rounding policy to round to the nearest $10 was applied to all amounts.

Table 3: Fees and charges 2021-22

Fees and charges for 2021-22	Type	Charge	Estimated volume	Estimated total revenue
Application for a cannabis licence (Single)	Fee	$8,030	20	$160,600
Applications for two cannabis licences (Double)*	Fee	$8,650	12	$103,800

Fees and charges for 2021-22	Type	Charge	Estimated volume	Estimated total revenue
Applications for three cannabis licences (Triple)*	Fee	$9,320	3	$27,960
Application to vary a cannabis licence – simple	Fee	$1,100	39	$42,900
Application to vary a cannabis licence – complex	Fee	$5,500	39	$214,500
Application for a cannabis permit	Fee	$3,440	63	$216,720
Application to vary a cannabis permit – simple	Fee	$120	426	$51,120
Application to vary a cannabis permit – complex	Fee	$2,900	26	$75,400
Planned Inspection	Fee	$3,670	23	$84,410
Annual licence charge	Levy	$12,010	125	$1,501,250
Annual site charge	Levy	$19,230	41	$788,430

*Fee applicable prior to 24 December 2021 only

The charges in Table 4 for non-compliance activities are indicative only. The actual charge will be based on the rate of **$108** per hour, calculated on the actual staff hours undertaken with each activity, charged in arrears. In addition, expenses incurred by the Department such as travel, accommodation, sampling testing and other associated expenses will be included in the charges payable for non-compliance follow up.

Table 4: Indicative charges for non-compliant activities

Indicative charges	Type	Charge	Estimated volume	Estimated total revenue
Follow up desk top auditing	Fee (at hourly rate)	$3,120	127	$396,240
Follow up inspection	Fee (at hourly rate + costs)	$6,630	64	$424,320
Follow up cannabis sample test	Fee (at cost)	$1,230	32	$39,360
Investigation	Fee (at hourly rate)	$8,860	13	$115,180
Investigation inspection	Fee (at hourly rate + costs)	$7,910	8	$63,280

Indicative charges	Type	Charge	Estimated volume	Estimated total revenue
Investigation cannabis sample test	Fee (at cost)	$1,230	4	$4,920
Enforcement Action – Minor	Fee (at hourly rate)	$4,440	89	$395,160
Enforcement Action – Moderate	Fee (at hourly rate)	$5,150	24	$123,600
Enforcement Action – Major	Fee (at hourly rate)	$7,010	11	$77,110

4. Risk assessment

A Charging Risk Assessment for the Scheme has been undertaken resulting in a **LOW RISK** rating.

This is attributed mainly to the small increase (less than 1%) in fees and charges. In addition, no complex legislative changes were required, and the stakeholders did not raise any issues about the indexation only increase.

5. Stakeholder engagement

In the 2019-20 financial year the Department undertook an extensive review of its cost recovery arrangements to develop an activity-based costing model in consultation with the Australian Government Department of Finance.

Once a preliminary version of the costing model and proposed fees and charges were developed, the Department embarked on a detailed program of stakeholder engagement. A number of stakeholder consultations, including face-to-face information and feedback forums, were conducted over a three-month period. Following this, the Department made further revisions to the costing model and cost recovery arrangements with a further public consultation paper published on the ODC website site, inviting written feedback on cost recovery arrangements.

Feedback provided during the stakeholder forums and through written submissions has been considered for the purposes of the finalising the costing model and cost recovery arrangements that were implemented in the 2020-21 financial year.

Further changes to the cost recovery arrangements to implement a single licence framework are expected in the 2021-22 financial year and will include stakeholder engagement prior to implementation.

The ODC website will be utilised to inform stakeholders about developments relating to the regulation of medicinal cannabis.

The medicinal cannabis sector is encouraged to provide ongoing feedback via email to mcs.application@health.gov.au.

6. Financial Estimates

Table 5: Financial estimate for 2021-22 and forward years

Financial estimate	2021-22 $'m	2022-23 $'m	2023-24 $'m	2024-25 $'m
Expenses = X	5.188	7.506	8.136	9.427
Revenue = Y	4.906	7.210	7.862	9.158
Balance = Y- Z	-0.282	-0.296	-0.274	-0.269
Cumulative balance	-1.693	-1.989	-2.263	-2.532
Explain balance management strategy	The Department has sought appropriation funding from the Australian Government to cover the cumulative balance variance resulting from partial cost recovery arrangements.			

7. Performance

7A. Financial performance

Table 6: Financial performance in previous years

Financial performance in previous years	2016-17 Actual $'m	2017-18 Actual $'m	2018-19 Actual $'m	2019-20 Actual $'m	2020-21 Actual $'m
Expenses = X	1.036	1.446	2.112	3.702	4.548
Revenue = Y	0.471	0.818	1.046	2.086	3.137
Balance = Y – X	-0.565	-0.628	-1.066	-1.616	-1.411
Cumulative Balance	-0.565	-1.193	-2.259	-3.875	-5,286
Notes on material difference	Partial cost recovery arrangements exist for non-commercial cannabis research licence holders whereby such licence holders pay one annual charge for the period the licence is in force as opposed to every year.				

7B. Non-financial performance

Table 7: Non-Financial performance of regulatory activity over previous years – Volumes

Activity	2017- 18 Estimated	2017-18 Actual	2017- 18 Variance	2018- 19 Estimated	2018- 19 Actual	2018- 19 Variance
Cannabis licence applications	18	49	31	15	95	80
Cannabis permit applications	36	11	-25	75	30	-45
Application for a variation to a cannabis licence	12	5	-7	40	30	-10
Application for a variation to a cannabis permit	30	2	-28	75	21	-54
Planned inspection hours	540	86	-454	180	19.75	-160,25
Annual charges	15	25	10	65	25	-40

Activity	2019-20 Estimated	2019-20 Actual	2019- 20 Variance	2020- 21 Estimated	2020- 21 Actual	2020- 21 Variance
Cannabis licence applications	31	63	32	20	12	-8
Cannabis permit applications	75	25	-50	63	34	-29
Application for a variation to a cannabis licence	40	67	27	78	91	13
Application for a variation to a cannabis permit	75	29	-46	452	49	-403
Planned inspection hours	360	26	-334	23	54	31
Annual charges	65	66	1	166	193	27

Reasons for variances

Each year the Department has underestimated the volume of applications submitted, which has had an impact on the number of cannabis licences and permits granted and broader workload of the Department. This can be attributed to the fact that the Scheme is regulating an emerging sector and it has been difficult to predict trends. Additionally, the sector has been financially impacted throughout 2020-21 by the COVID-19 pandemic which has resulted in a lower than anticipated number of new licence and permit applications.

There is a link between the variance in cannabis permit applications and the number of hours estimated for planned inspections. Such an inspection only occurs after a medicinal cannabis permit application has been submitted and, as previously stated there is a lead-time of approximately 18 months between the date in which a medicinal cannabis licence is granted and the time in which a site is ready for inspection. This scenario has been factored into the existing costing model and should be more accurately reflected for future years. Similarly, this has an impact on the volume of applications to vary a medicinal cannabis licence or permit variations that are submitted. Additionally, the COVID-19 pandemic has had an impact on compliance activities requiring travel and may continue to do so particularly for the year ahead.

Performance measures

The Narcotic Drugs Act does not include statutory timeframes for decision-making or application processing. The Department provides an indicative timeline for processing applications on the ODC website, from the date of receipt. However, this excludes any time where the application is referred back to the applicant for further information.

Prior to the commencement of the single licence and related permit reforms on 24 December 2021, the published timeframes were:

- cannabis licence application - approximately 210 days
- application to vary a cannabis licence: Simple – approximately 70 days
- application to vary cannabis licence: Complex – approximately 210 days

However, the Department anticipates the implementation of the medicinal cannabis licence and permit reforms in late 2021, including the related legislative amendments, will result in a reduction in the assessment periods for medicinal cannabis licences and permits from these previous timeframes.

The Department is in the preliminary stages of developing an IT based system that will keep records of dates specific to the assessment of applications and other regulatory decision process. This system will allow for the efficient and accurate reporting on such data, which can be utilised to update guidance available to applicants on the ODC website as well as assisting in the development of remediation strategies for pressure points in the regulatory processes. It is intended that this will save time in the assessment process.

International Scrutiny

The progress of the Scheme will be the subject of scrutiny from the INCB. Australia is required to provide annual datasets to the INCB outlining the quantities of cannabis plants cultivated, cannabis and cannabis resin that has been produced and cannabis drugs that have been manufactured in a calendar year.

The INCB then makes comments in its annual report on the performance of Australia against the requirements of the Single Convention. If the INCB make a negative comment on Australia's performance, for example that production of cannabis resin has exceeded the medical need, then remedial action may need to be considered. Such an event could impact on the data provided in this document.

8. Key forward dates and events

- Jan-June 2022 – Review of the cost recovery model and fees and charges will be conducted in light of the revised legislative framework and in accordance with the Australian Government Charging Framework.
- The Department's portfolio charging review for input into the 2023-24 Budget.

9. CRIS approval and change register

Table 8: CRIS Approval and Change Register

Date of CRIS change	CRIS change	Approver	Basis of change
21 October 2016	Certification of the CRIS	Secretary Department of Health	New regulatory charging activity
02 November 2016	Agreement of the CRIS	Minister for Health	New regulatory charging activity
10 November 2016	Approval for the CRIS release	Finance Minister	High risk rating for the new regulatory charging activity
16 April 2019	Update of financial results and estimates.	Secretary Department of Health	2016-17 and 2017-18 financial results reported. 2018-19 and forward estimates updated.
20 March 2020	Update of 2018/19 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2018/19 financial results reported.
October 2020	Revision of fees and charges to reflect review of cost recovery arrangements and changes announced in 2020-21 Budget.	Minister for Health	Review of cost recovery cost recovery arrangements. Revised and new fees and charges.

Date of CRIS change	CRIS change	Approver	Basis of change
July 2021	Annual update of CRIS and application of indexation to fees and charges for the 2021-22 financial year	Minister of Health and Aged Care	Annual update and review.
December 2021	Update of 2020-21 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2020/21 financial results reported