



Cost Recovery Implementation Statement (CRIS) Regulation of Medicinal Cannabis 2020-21

Effective from 1 November 2020

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*.

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

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1. Introduction

Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the 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 Narcotic Drugs Act).

This CRIS reports financial and non-financial performance information for regulation of medicinal cannabis and contains financial forecasts for 2020-21 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

The Department implemented and continues to administer the Scheme which is a licence and permit framework that allows for the cultivation, production and manufacture of medicinal cannabis in Australia in accordance with Australian legislation and international obligations. This is to ensure Australian patients have access to essential medicine while supporting the Australian Government policy of harm minimisation.

For the purposes of this document, the Scheme cost recovery arrangements (hereafter the cost recovery arrangements) **only** apply to:

- medicinal cannabis licences and permits;
- cannabis research licences and permits;
- cannabis-related manufacture licences and permits; and
- compliance activities related to such licences and permits.

For further clarity the following activities, as far as they relate to medicinal cannabis, are not included in the cost recovery arrangements as these activities are conducted under separate legislation.

The Scheme contributes to the delivery of Outcome 5 of the Portfolio Budget Statement (the PBS) for the Department. The purpose of the PBS is to inform Senators and Members of Parliament of the proposed allocation of resources to Government outcomes by agencies within the relevant portfolio.

Outcome 5: Regulation, Safety and Protection

Protection of the health and safety of the Australian community and preparedness to respond to national health emergencies and risks, including through immunisation, initiatives, and regulation of therapeutic goods, chemicals, gene technology, and blood and organ products

5.1: Protect the Health and Safety of the Community through Regulation

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 those 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.

Australia is a party to the *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol* (the Single Convention). At a high level, this convention aims to limit the harm done by 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 Narcotic Drugs 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 a lawful supply of medicinal cannabis to Australian patients. The Act, as amended, 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 single 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 cost recovery arrangement.

Outline of the regulatory activities

Cannabis licences

An applicant may make an application for a medicinal cannabis licence, a cannabis research licence or a cannabis-related manufacture licence (hereafter cannabis licences) and 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 such a decision, a Delegate must be reasonably satisfied of a number of factors:

- The applicant and the applicant's relevant business associates must be considered a fit and proper person 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.

Cannabis permits

- Once a licence is granted, a licence holder must undertake the activities authorised under a 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 a Delegate will set limitations on the scope of the activities that can be undertaken for example, but not limited to:
 - The quantity of cannabis plants can be cultivated;
 - The quantity of cannabis and/or cannabis resins can be produced; or
 - 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 to 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 offences and contravention of provisions that involve breaches of conditions and the undertaking of activities that are not authorised by or under 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 regulate the cultivation of cannabis for medicinal and scientific use, to be administered by the Department².

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 *Narcotic Drugs Act 1976*. Any revenue collected will support the Scheme for the regulation of cannabis for medicinal and scientific use.³

As a result of the unanticipated 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 arrangements⁴. This was the trigger for the review into the cost recovery arrangements, which is discussed in Section 3.

In the 2020-21 Budget, the Government announced the extension of the cost recovery arrangements to cannabis-related manufacture licences, and increased resourcing to meet the ongoing demands of administering the Scheme.

There will be no change to the partial cost recovery arrangements that relate to cannabis research licences for non-commercial purposes. Full recovery of direct costs for administering non-commercial cannabis research licences risks the stifling of research. The balance of these costs will be met through appropriation from the Australian Government.

Statutory authority to charge

The *Narcotic Drugs Act*⁵ allows for Regulations to 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 *Narcotic Drugs Act* and that is in force within a specified period. The imposition of a charge on a licence that is in force assists the Commonwealth in recovering the costs of the administration, monitoring and assessment of compliance with the requirements under the *Narcotic Drugs Act*, after the cannabis licence and permits associated with the cannabis licence are granted. Section 9 of the *Licence Charges Act* allows Regulations to be made to prescribe matters to give effect or carry out the Act.

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 Budget Measures Budget Paper No. 2 2016-17, https://archive.budget.gov.au/2016-17/bp2/BP2_consolidated.pdf, p.118.

⁴ Mid-Year Economic and Fiscal Outlook 2018-19, https://archive.budget.gov.au/2018-19/myefo/myefo_2018-19.pdf, p.189.

⁵ *Narcotic Drugs Act 1967*, Section 28 (1)(c),(d) and (e).

The *Narcotic Drugs (Licence Charges) Regulation 2016* (the Licence Charges Regulation) specifies the period in which the charge is imposed, the amount of the charge and how the charge is calculated. It also provides for non-commercial cannabis research and non-commercial cannabis-related manufacture 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 cannabis research licence is defined in section 54(2)(a) of the Narcotic Drugs Regulation.

Statutory Review of the Narcotic Drugs Act 1967

In 2018, in accordance with section 26A of the Narcotic Drugs Act, the Hon Greg Hunt MP appointed Professor John McMillan AO to conduct a review and provide a report on the operation of the Narcotic Drugs Act. The Report on the Review of the *Narcotic Drugs Act 1967* (the Report) was tabled in Parliament as required, 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, 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. Amendments to the Narcotic Drugs Regulation were implemented on 01 January 2020 to streamline the application process. Amendments to the Narcotic Drugs Act to allow for a single cannabis licence that authorises one or more activities that are currently authorised under separate licence types is expected to be introduced as a Bill into the Parliament of Australia in late 2020.

If the Bill is passed by Parliament as proposed, the costing model underpinning this document will require amendment. The relevant parties affected by this will be engaged either through face to face engagement (if the circumstances at the time allow) or through a publically available consultation paper.

3. Cost recovery model

Revised cost recovery arrangements

As a result of an extensive activity based costing review (the charging review) for the Scheme undertaken in the 2019-20 financial year, the Department revised the cost recovery arrangements for the first time since the Scheme commenced. To conduct the charging review, in accordance with the Australian Government Cost Recovery Guidelines (hereafter the Cost Recovery Guidelines), the Department identified the efficient costs of undertaking an activity.⁶ Efficient costs are based on the average efficient time taken by a reasonable member of staff in performing the function. These costs were then compared with the costs recovered from applicants and licence holders. The key findings of the charging review were:

- In order to adequately resource the Department, and remove any cross subsidisation, the Department should recover the costs of assessment and compliance activities associated with cannabis-related manufacture licences.
- The cost and structure of the fees and charges did not effectively recover the regulatory costs for the Department to administer the Scheme.
- The fee structure did not account for the effort to assess applications for complex and simple variations to licences.
- The cost of fees for multiple applications did not consider efficiencies obtained through simultaneous assessment of these applications (where appropriate).

⁶ Australian Government Cost Recovery Guidelines, p. 14.

- The annual charge did not differentiate between a licence holder's compliance history meaning those that are highly compliant pay the same charges as those who are non-compliant, despite non-compliance requiring greater effort by the Department.
- Indexation of fees and charges should occur annually but had not been adjusted since introduction of the Medicinal Cannabis Scheme in 2016.

As a result of the charging review, the Department developed a proposal for amendments to fees and charges for the Scheme and undertook a detailed program of stakeholder engagement. Once the stakeholder engagement was completed, the Department sought and received approval from the Minister for Health to commence the implementation of the amended fees and charges for commencement from 15 July 2020. The 2020-21 Budget (delivered in October 2020) outlined further changes to fees and charges commencing from 1 November 2020.

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.
2. Inspections.
3. Annual licence charge.
4. Annual site charge.
5. Non-compliance follow up.

Business processes to deliver key outputs

The business processes described below are categorised to allow similar business processes to be described 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.

1. Receipting which includes filing all documentation and handling payment of invoices.
2. Qualitative screening of the applications.
3. Assessment of the application.
4. Decision by a delegate to grant or refuse to grant a cannabis licence, permit, or variation to a cannabis licence or permit.
5. Notification of decision made.

Application for a cannabis licence

Any person interested in undertaking cultivation, production or cannabis-related manufacture under the Scheme must apply for a cannabis licence and a Delegate must make a decision on the application. While each 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 cannabis licence type was comparable. The assessment of a cannabis licence application includes consideration of the applicant as a fit and proper person to hold a cannabis 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.

The simultaneous handling of multiple cannabis licence applications, submitted by the same person for the same site, creates efficiencies. As a result, three different fees exist for the submission of cannabis licence applications that reflects the number of applications submitted at one time, for a single site.

1. Application for a cannabis licence (a single application).
2. Applications for two cannabis licences (double applications).
3. Applications for three cannabis licences (triple applications).

Application to vary a cannabis licence

A licence holder can apply to vary a 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 cannabis licence is divided into two categories.

1. Application to vary a cannabis licence – simple.
2. Application to vary a cannabis licence – complex.

The specifications of simple and complex cannabis licence variations are outlined in a document that is available on the ODC website. The document is titled 'Specification of variation applications'. This document may be varied from time to time and is available to use.

While cannabis licences have a specified period during which they are in force, the Department has adopted a policy of extending the period a cannabis licence is in force, without the need to apply for a new cannabis licence. This reflects the intention of the Department whereby cannabis licences will be in force for perpetuity. As these variations require effort on the part of the Department, such amendments will require the applicant to apply for a *simple* cannabis licence variation and pay the relevant fee.

Application for a cannabis permit

Any activities authorised under a cannabis licence must be undertaken in compliance with a valid cannabis permit. As such, once a cannabis licence is granted, a licence holder may apply for one or more cannabis permit. 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 cannabis permit is a critical tool in ensuring Australia complies with its international obligations under the Single Convention. The assessment of a 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.

Note on cannabis permit applications: As cannabis permit applications cannot be assessed simultaneously in the way that cannabis licence applications can there is no efficiency gained from the simultaneous submission of such applications. This is why there is only a single cannabis permit application fee.

Applications to vary a cannabis permit

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

1. Application to vary a cannabis permit – simple.
2. Application to vary a cannabis permit – complex.

The specifications for simple and complex cannabis permit variations are also outlined in the 'Specification of variation applications' document on the ODC website.

3.1.2 Output 2 - Inspections

An inspection is undertaken to physically verify matters relating to cannabis licences or permits. While the business processes related to such inspections are the same, the effort required for undertaking such inspections differs. 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.

The following activities are associated with all inspections:

1. Plan and book.
2. Travel.
3. Conduct inspection.
4. Finalise inspection.
5. Notification and follow up.

Planned inspections: Upon the grant of a cannabis licence and prior to the grant 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 cannabis licence and is in accordance with the proposed site/facility plans provided with the application. It is a pre-requisite for a cannabis permit application that a planned inspection of the site has been conducted.

Historical data has proven that all planned (pre-permit) inspections occur within a similar timeframe and are shorter in duration to later inspections as there are usually no cannabis plants, cannabis or cannabis resin on site at the time of the 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 it 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 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 accommodations, 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 some within remote parts of the State. 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 such 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 such 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. Such samples are tested in the Therapeutic Goods Administration (TGA) Laboratory 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 \$1,200 and this is passed directly to the licence holder.

3.1.3 Output 3 – Annual licence charge

The annual licence charge covers the costs of three activities.

1. Response to mandatory notification.
2. Public concern (tip off) inspections – refer to section 3.1.2.
3. 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 certain matters. As the Department must respond to such notifications, the cost of such responses are included in charges to licence holders. Not all matters will be a matter of non-compliance however; the Department must review the 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.

1. Receive and register the notification.
2. Review and analyse the notification.
3. Make determination on matter.
4. Where relevant, refer matter of potential non-compliance to the relevant team for action.
5. 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 is a business process that has been incorporated into the cost recovery arrangements. The following activities are associated with this business process.

1. Legislative reform and the associated processes.
2. Development and maintenance of publically available guidance.
3. Stakeholder engagement activities.
4. Activity based costing processes and ongoing management of the cost recovery arrangements.

3.1.4 Output 4 – Annual site charge

The annual site charge covers the costs of four activities.

1. Compliance monitoring inspection – refer to section 3.1.2.
2. Cannabis permit reporting.
3. Education and corrective action.
4. 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 and the following activities are associated with this task.

1. Receive and register reports.
2. Review and analyse the report/s.
3. Make determination on matter.
4. Where relevant, refer matter of potential non-compliance to the relevant team for action.
5. 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.

1. Receive and review matter.
2. Liaise with licence holder.
3. Where relevant, provide documentation outlining corrective action to licence holder.
4. Reconcile evidence that corrective action has been undertaken.
5. Where relevant, refer matter of potential non-compliance to the relevant team for action.
6. 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.

1. Receive and review matter.
2. Document facts of matter, and assess risk.
3. Develop audit plan.
4. Gather documentary evidence.
5. Analyse data and complete report.
6. Where relevant, refer matter of potential non-compliance to the relevant team for action.
7. Notify licence holder of outcome.

Investigations

While inspections and testing of cannabis samples are related to investigations, a significant amount of work is undertaken within the office when undertaking an investigation. The following activities are associated with the in-office component of an inspection.

1. Receive and review matter.
2. Document facts of matter, and assess risk.
3. Develop investigation plan.
4. Gather documentary evidence.
5. Prepare brief of evidence.
6. Finalise report.

Enforcement action

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

1. Receive and review matter.
2. Assess the non-compliance and information available.
3. Review compliance history.
4. Decision.
5. Notification.

The Enforcement Actions have been 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 this 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 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 Narcotic Drugs 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 cannabis licence or permit as provided for in section 11A of the Narcotic Drugs 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 cannabis licence or permit as provided for in section 10P of the Narcotic Drugs Act.

3.2 Costs of the regulatory charging activity

Activity based costing

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

Tables 1 and 2 summarise the direct and indirect costs of each fee and charge for the 2020-21 financial year.

Cost drivers and assumptions

In determining the cost drivers associated with the activities a number of assumptions were made based on the historical data and experience from undertaking such activities. The Department analysed the trends in volumes of applications received, time take to undertake specific activities and the behaviours of the medicinal cannabis sector in predicting future volumes. A specific example is that, from experience, the Department determined the average time from the point at which a 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 estimations 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	Direct Costs	Indirect costs	Total costs
<i>Output 1 – Applications</i>			
Application for a cannabis licence (Single)	\$6,383	\$1,581	\$7,964
Applications for two cannabis licences (Double)	\$6,873	\$1,705	\$8,578
Applications for three cannabis licences (Triple)	\$7,408	\$1,838	\$9,246
Application to vary a cannabis licence – simple	\$853	\$234	\$1,087
Application to vary a cannabis licence – complex	\$4,396	\$1,065	\$5,461
Application for a cannabis permit	\$2,761	\$653	\$3,414
Application to vary a cannabis permit – simple	\$95	\$27	\$122
Application to vary a cannabis permit – complex	\$2,326	\$547	\$2,873
<i>Output 2 – Planned Inspection</i>	\$2,905	\$741	\$3,646
<i>Output 3 - Annual licence charge*</i>	\$9,585	\$2,294	\$11,879
<i>Output 4 – Annual site charge*</i>	\$15,942	\$3,103	\$19,045

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 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) and an annual site charge which is charged annually for each site.

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)	Direct Costs	Indirect costs	Total costs
Follow up desk top auditing	\$2,507	\$585	\$3,092
Follow up inspection	\$5,638	\$899	\$6,537
Investigation	\$7,061	\$1,783	\$8,799
Investigation inspection	\$6,667	\$1,143	\$7,810
Enforcement action – Minor	\$3,614	\$782	\$4,396
Enforcement action – Moderate	\$4,202	\$897	\$5,099
Enforcement action - Major	\$5,723	\$1,219	\$6,942

Table 3 lists the fees and charges payable in the 2020-21 financial year and the estimated revenue for this financial year.

Note: The charges in Table 3 for non-compliance activities are indicative only. The actual charge will be based on the rate of \$107 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 3 – Fees and Charges for 2020-21	Type	Charge	Estimated volume	Estimated total revenue
Application for a cannabis licence (Single)	Fee	\$7,960	20	\$159,200
Applications for two cannabis licences (Double)	Fee	\$8,580	12	\$102,960
Applications for three cannabis licences (Triple)	Fee	\$9,250	3	\$27,750
Application to vary a cannabis licence – simple	Fee	\$1,090	39	\$42,510
Application to vary a cannabis licence – complex	Fee	\$5,460	39	\$212,940
Application for a cannabis permit	Fee	\$3,410	63	\$214,830
Application to vary a cannabis permit – simple	Fee	\$120	426	\$51,120
Application to vary a cannabis permit – complex	Fee	\$2,870	26	\$74,620
Planned Inspection	Fee	\$3650	23	\$83,950

Table 3 – Fees and Charges for 2020-21	Type	Charge	Estimated volume	Estimated total revenue
Annual licence charge	Levy	\$11,880	125	\$1,485,000
Annual site charge	Levy	\$19,050	41	\$781,050
Non-compliance activities				
Follow up desk top auditing	Fee (at hourly rate)	\$3,090	127	\$392,430
Follow up inspection	Fee (at hourly rate + costs)	\$6,540	64	\$418,560
Follow up cannabis sample test	Fee (at cost)	\$1,200	32	\$38,400
Investigation	Fee (at hourly rate)	\$8,800	13	\$114,400
Investigation inspection	Fee (at hourly rate + costs)	\$7,810	8	\$62,480
Investigation cannabis sample test	Fee (at cost)	\$1,200	4	\$4,800
Enforcement Action – Minor	Fee (at hourly rate)	\$4,400	89	\$391,600
Enforcement Action – Moderate	Fee (at hourly rate)	\$5,100	24	\$122,400
Enforcement Action – Major	Fee (at hourly rate)	\$6,940	11	\$76,340

4. Risk assessment

A Charging Risk Assessment for the Scheme has been undertaken resulting in a **MEDIUM RISK** rating. This is attributed to materiality of the cost recovery arrangements for individuals or companies, specifically, the:

- the significant increase in annual revenue; and
- the substantial nature of the amendments to the cost recovery arrangements, which has an impact on the payers of the fee and charges.

These higher-level risks are tempered by the fact that the cost recovery arrangements are not complex in the sense that such change did not require changes to primary legislation or involve engagement with other Commonwealth, State/Territory and/or local Government entities make the cost recovery arrangements lower in risk. Further, with regard to sensitivities, the significant stakeholder engagement undertaken by the Department on the revised cost recovery arrangements allowed for the medicinal cannabis sector and other interested parties to raise concerns with the proposed cost recovery arrangements and influence the structure of the cost recovery arrangements. The result is that there is broad support for the revised cost recovery arrangements.

5. Stakeholder engagement

The Department has undertaken an extensive review of its cost recovery arrangements and the development of an activity based costing model has been undertaken in consultation with the 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 in the 2019-20 financial year. There was a range of stakeholder consultations, including face-to-face information and feedback forums conducted over a three-month period on the east coast of Australia.

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.

The ODC website will be utilised to keep stakeholders abreast of the latest 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 4 – Financial estimate for 2020-21 and forward years	2020-21 \$'m	2021-22 \$'m	2022-23 \$'m	2023-24 \$'m
Expenses = X	5.137	6.775	7.717	8.122
Revenue = Y	4.857	6.241	7.187	7.847
Balance = Y- Z	-0.280	-0.534	-0.529	-0.275
Cumulative balance	-0.280	-0.814	-1.343	-1.619
Explain material variance	This variance is attributed to the partial cost recovery arrangements which exist for non-commercial cannabis research licence holders whereby those licence holders pay their annual charge for the entire period the cannabis licence is in force at the commencement of the cannabis licence as opposed to every year.			
Explain balance management strategy	The Department has sought appropriated funding from the Australian Government to cover the cumulative balance variance resulting from partial cost recovery arrangements.			

7. Performance

7A. Financial performance

Table 5 – Financial performance in previous years	2016-17 Actual \$'m	2017-18 Actual \$'m	2018-19 Actual \$'m	2019-20 Actual \$'m
Expenses = X	1.036	1.446	2.112	3.702
Revenue = Y	0.471	0.818	1.046	2.086
Balance = Y – X	-0.565	-0.628	-1.066	-1.616
Cumulative Balance	-0.565	-1.193	-2.259	-3.875
Notes on material difference	This variance is attributed to the current partial cost recovery approach in which cannabis-related manufacture licences and permits are not subject to fees or charges. Additionally, 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 6 – Non-Financial performance of regulatory activity over previous years – Volumes									
Activity	2017-18 Estimate	2017-18 Actual	2017-18 Variance	2018-19 Estimate	2018-19 Actual	2018-19 Variance	2019-20 Estimate	2019-20 Actual	2019-20 Variance
Cannabis licence applications	18	49	31	15	95	80	31	63	32
Cannabis permit applications	36	11	-25	75	30	-45	75	25	-50
Application for a variation to a cannabis licence	12	5	-7	40	30	-10	40	67	27
Application for a variation to a cannabis permit	30	2	-28	75	21	-54	75	29	-46
Planned inspection hours	540	86	-454	180	19.75	-160.25	360	26	-334
Annual charges	15	25	10	65	25	-40	65	66	1

Reasons for variances

Each year the Department has underestimated the volume of applications submitted which has 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. The Department had expected that the sector would stabilise at some point and the volume of applications would plateau however, this has not happened.

The estimates provided for the 2020-21 financial year (outlined in Table 2) should provide a more accurate picture of the expected workload given the Department now has a larger dataset to refer to in predicting trends.

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 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 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 cannabis licence or permit variations that are submitted.

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.

- Cannabis licence application - Approximately 210
- Application to vary a cannabis licence: Simple – Approximately 70 days
- Application to vary cannabis licence: Complex – Approximately 210 days

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, once completed, 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. The Government, through the ODC, is required to provide annual datasets to the INCB outlining the actual quantities of cannabis plants cultivated, cannabis and cannabis resin that has been produced and cannabis drugs that have been manufactured in Australia 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. Should 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

- 1 November 2020 new/updated fees and charges come into effect.
- June 2021 – publish the 2021-22 CRIS.
- November 2021 – update the CRIS to report 2020-21 financial year results.
- 2022 – The Department's portfolio charging review for input into the 2023-24 Budget.

9. CRIS approval and change register

Table 7 – CRIS Approval and Change Register			
Date of CRIS change	CRIS change	Approver	Basis of change
21/10/2016	Certification of the CRIS	Secretary Department of Health	New regulatory charging activity
02/11/2016	Agreement of the CRIS	Minister for Health	New regulatory charging activity
10/11/2016	Approval for the CRIS release	Finance Minister	High risk rating for the new regulatory charging activity
16/04/2019	Update of financial results and estimates	Secretary Department of Health	2016-17 and 2017-18 financial results reported. 2018-19 and forward estimates updated
20/3/20	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 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.