

Medicinal Cannabis Program Proposed Fees and Charges

20 December 2022



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Assistant Secretary
Office of Drug Control
Branch Health Products
Regulation Group



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Group



Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Welcome

Housekeeping

- This webinar is being recorded
- Today presentation will be made available in the ODC website in the upcoming weeks
- Any relevant links will be broadcasted via the slido app
- Q&A session will occur after todays presentation
- Live poll – how did we go, let us know



Difficulties hearing from computer?

Check your settings located under
“**Audio & Video**” tab located top of your screen:

OR

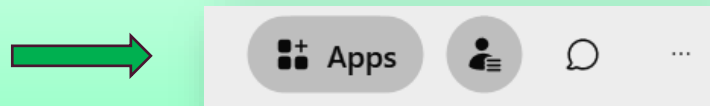
Dial: 02 9338 2221 (+61-2-9338-2221)

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How to ask questions

SLIDO

Slido App



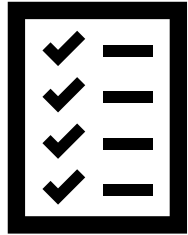
- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

Slido QR

Scan the QR
code to access
separately from
your mobile
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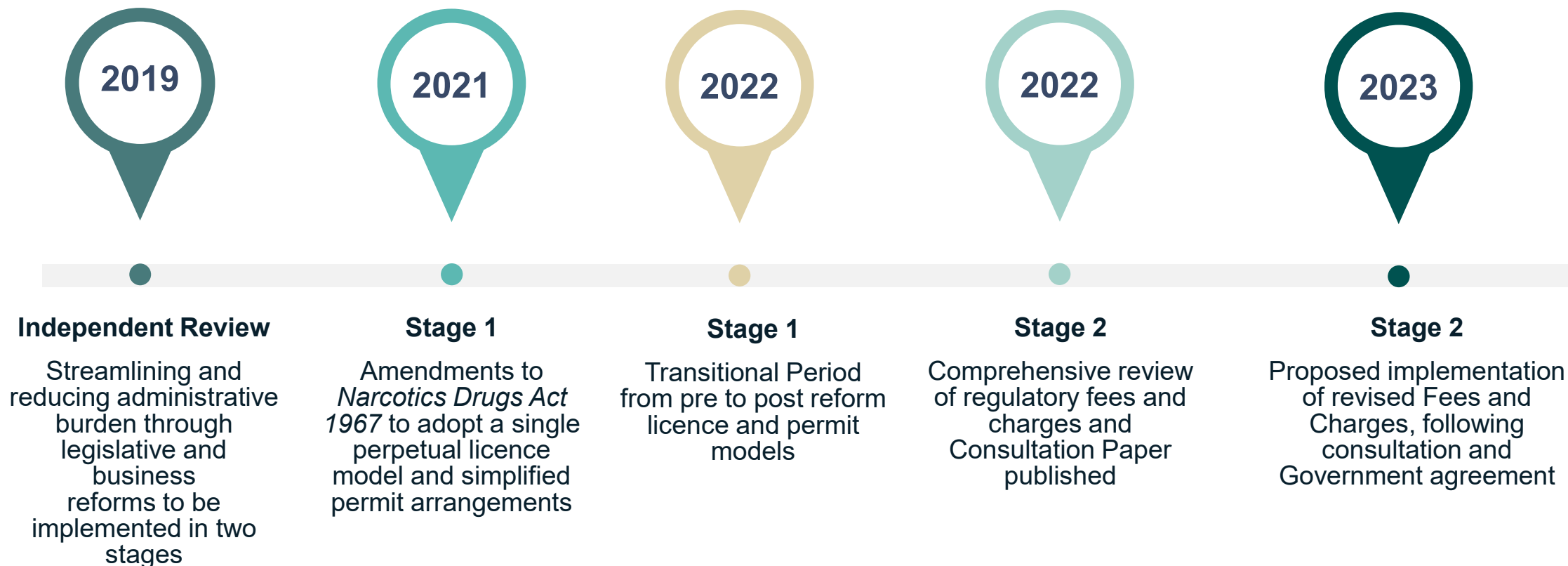


Key Discussion Points



- Overview of the Consultation Paper
 - Medicinal Cannabis Program Regulatory Fees and Charges Review
- Medicinal Cannabis Reforms
- Charging for Regulatory Activities
- Proposed New Fees and Charges
- Hypothetical Regulatory Pathway
- Further Information and Contact Details
- Questions

Medicinal Cannabis Reforms Timeline



Charging for Regulatory Activities



Decisions to Cost Recover Medicinal Cannabis Regulation

- Cabinet decisions to cost recover regulatory activities



Requirements for Regulators

- Regulator Performance Guidelines
- Regulatory settings are not 'set and forget'
- Focus on reducing regulatory burden on industry



Australian Government Charging Framework

- AGCF Charging Policy Statement : 'Those that create effort, should pay the cost of that effort'
- Transparent and accountable Fees and Charges
- Minimum Efficient Costs through an Activity Based Costing Model

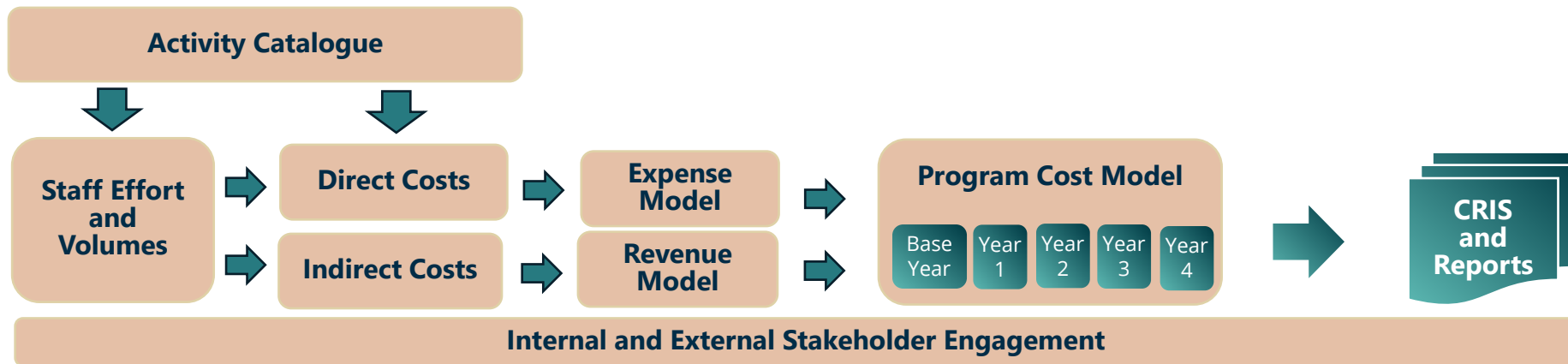


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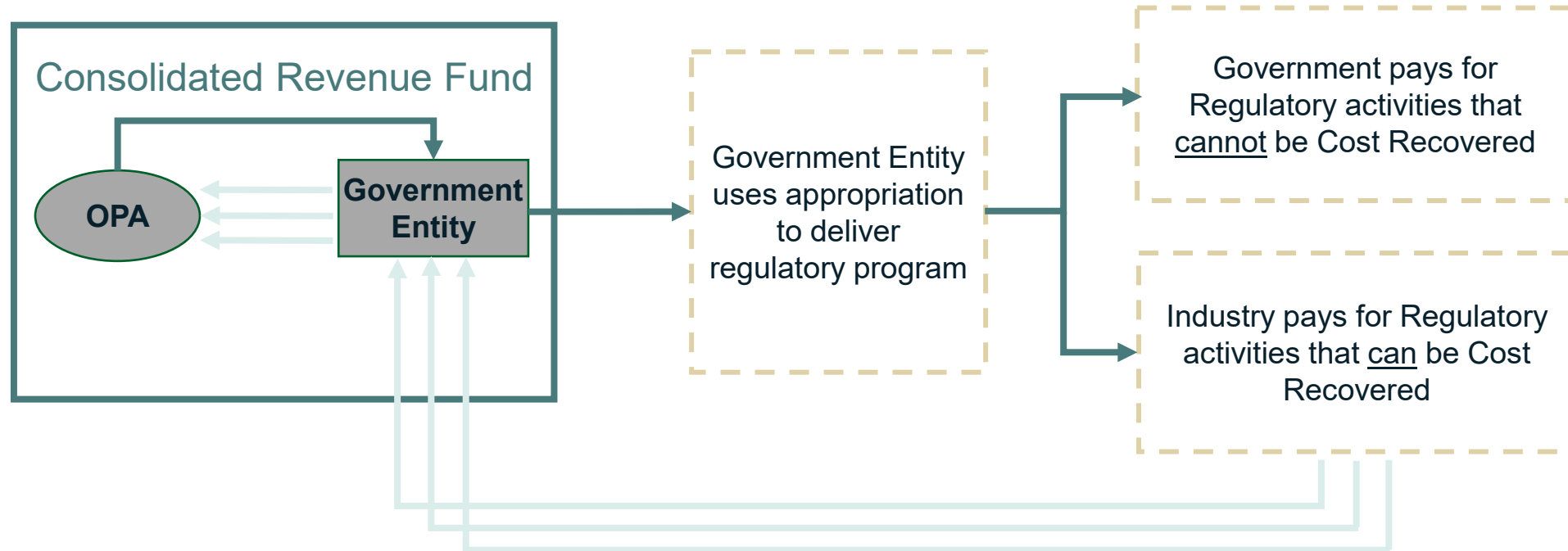
Charging for Regulatory Activities

Key Elements of the ODC Activity Based Cost Model



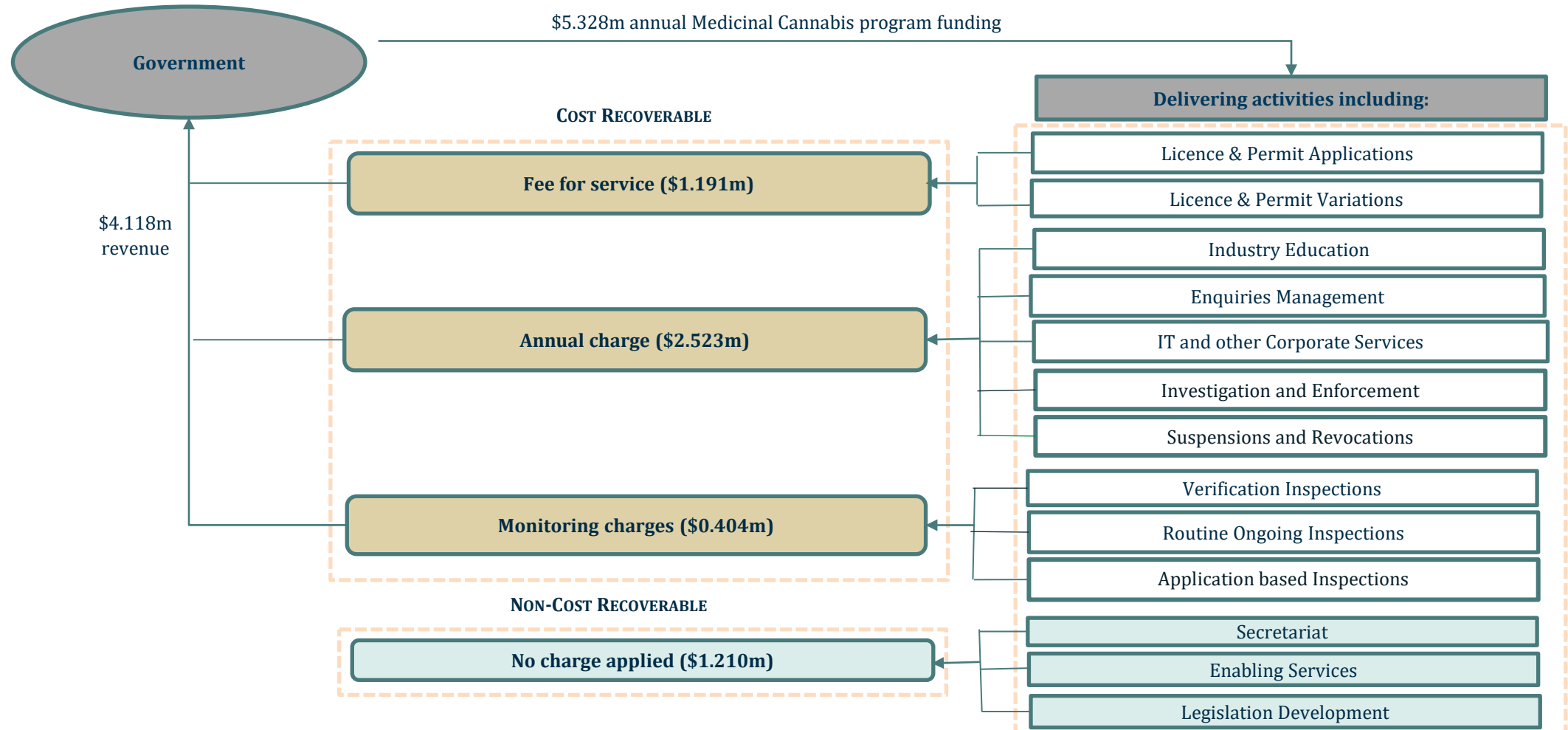
An ABC Model delivers a Transparent Regulatory Cost Base = Minimum Efficient Costs

Charging for Regulatory Activities



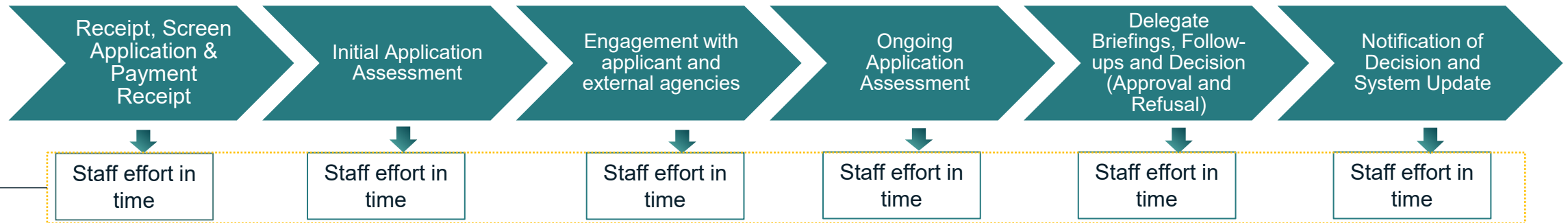
OPA: Official Public Account – Government’s Official Bank Account

Medicinal Cannabis Funding Model



Charging for Regulatory Activities

Licence Application (High Level) Key Business Processes - Example



Costing Process

- Each Business Process expends a level of regulatory effort
- Regulatory staff effort is measured in time and then converted to costs (Direct Costs)
- An overhead component is applied to the staff effort (Indirect Costs)
- Direct and Indirect Costs determines the unit cost of an application assessment
- As this is a Fee-for-Service charging item the unit cost is then translated into a price point
- The proposed price for a Licence Application in 2023 is \$12,263.

Proposed New Fees and Charges

Some key changes

Annual licence charge

- Annual licence charge increases from \$12,010 to \$26,559
- Applies annually to all licence holders

Annual site charge

- Annual site charge to be removed, so permit holders will no longer pay \$19,230 in addition to the annual charge
- Some compliance activities previously covered by the annual site charge will now be separate inspection charges

Compliance Activities

- Previous pre-commissioning inspection fee (\$3,670) and monitoring and compliance activity charge (\$108/hr rate) replaced by specific inspection categories
- Inspections charged when they occur, on a risk-based compliance approach

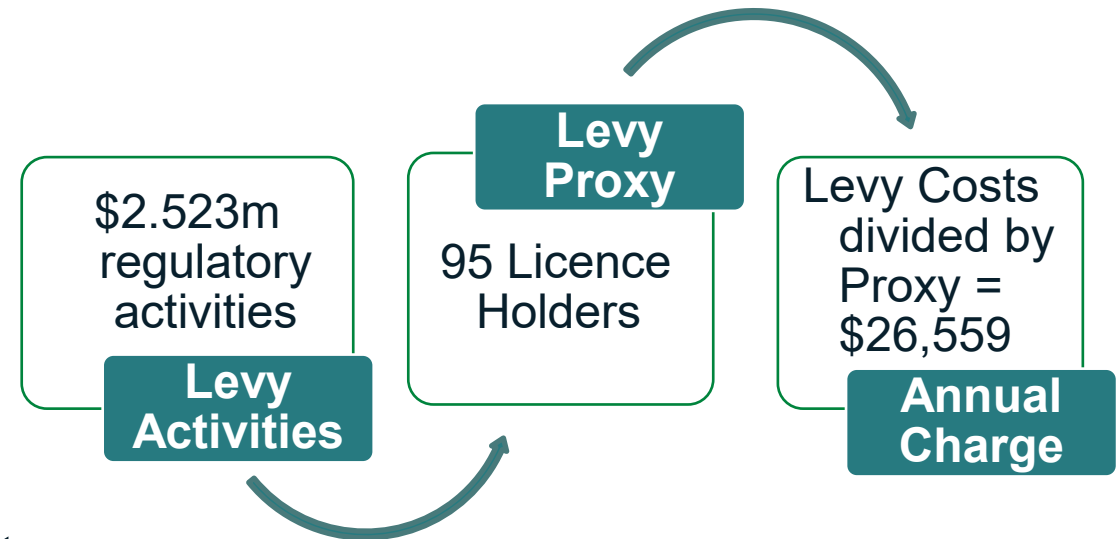
Licence and Permit Variations

- Variation applications that cost similar amounts to be grouped together as a 'type'
- Applications to be targeted to the specific change/s to be made, so more reflective of the cost of the work

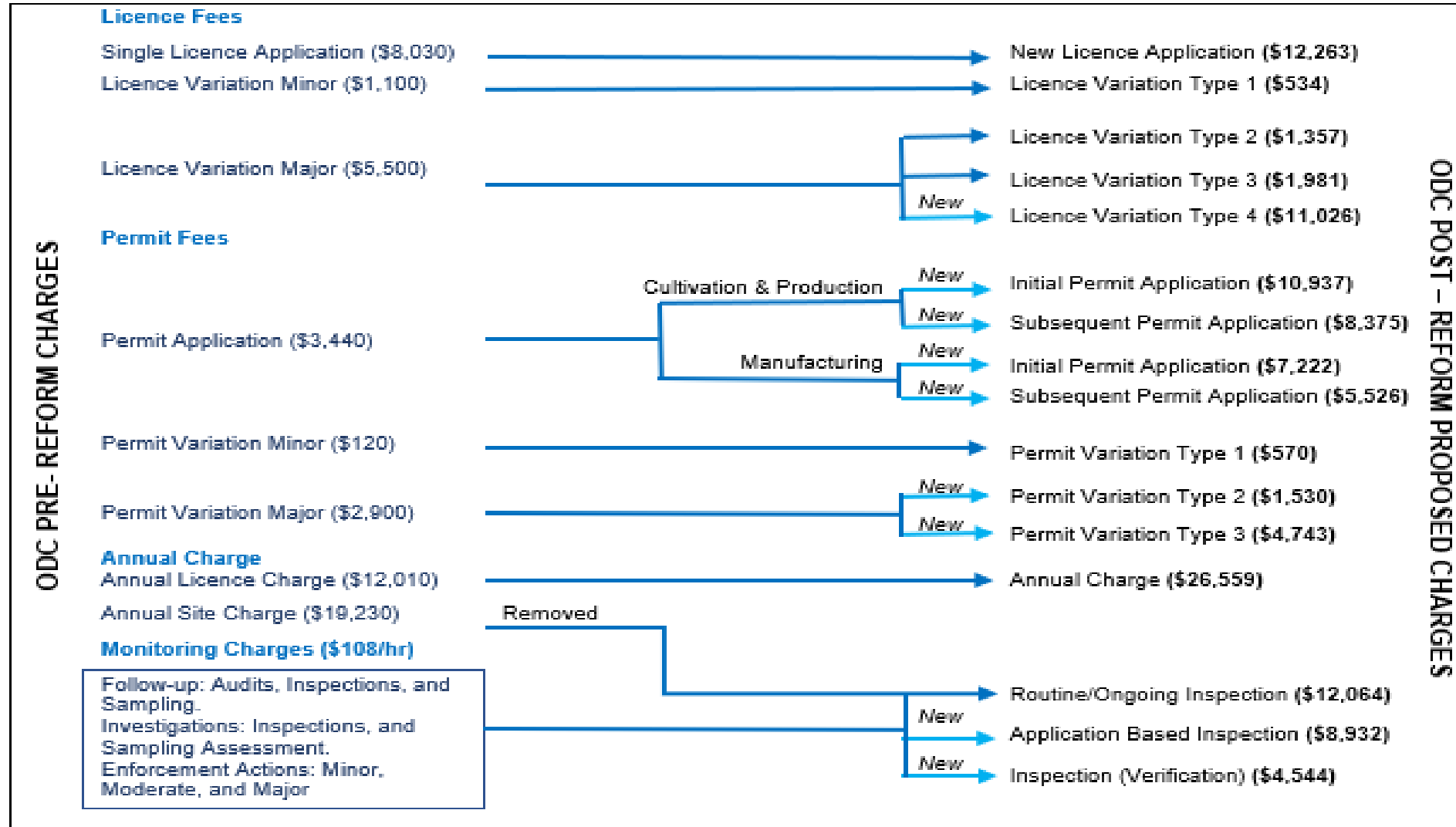
Charging for Regulatory Activities

Annual Charge Example – Cost Recovery Levy

- Cost recovery levies: Used to recover regulatory activities from a group of Licence Holders rather than an individual Licence Holder.
- Examples of levy activities include:
 - Enquiries management
 - Industry Education
 - Regulatory oversight, and
 - IT and Corporate costs.
- Levy activities costed in the same way as Fee for Service activity – Minimum Efficient Costs.
- Levy proxy used to apportion levy costs across the group.



Proposed New Fees and Charges



Proposed New Fees and Charges

Category Types

- It is proposed that variation applications that consume similar effort (i.e., cost) be grouped together.
- Proposed Variation Types reflect similar regulatory effort and therefore proposed to be charged at the same price.
- Variation Types exist across both Licence and Permit variations.
- Licence Holders will be required to pay for each variation requested

Category Types

Licence Variation Type 1 (\$534 each):

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

Licence Variation Type 2 (\$1,357 each):

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

Licence Variation Type 3 (\$1,981 each):

- Change of layout of site
- Change of floorplan of facility
- Add activity to licence
- Add authorised person/s

Licence Variation Type 4 (\$11,026):

- Add Additional Site

Permit Variation Type 1 (\$570 each):

- Change to licence holder business name
- Change to maximum quantity at any one time with no change to total quantity

Permit Variation Type 2 (\$1,530):

- Change to supply pathways only

Permit Variation Type 3 (\$4,743):

- Change to quantities or activities



Example of how variation fees will be applied

Licence holders will be required to pay for each variation requested

Scenario

- A licence holder applies to vary their licence to account for changes in the floorplan of a facility. Due to the change in floorplan, security measures were modified to adjust to the change in floorplan.

Type of variations that apply to this scenario

- Licence variation Type 2 – Modify or remove security measures
- Licence variation Type 3 – Change of floorplan of facility

Applicable fees to licence holder

- \$1,357 (type 2) + \$1,981 (type 3)
- A total fee of \$3,338 would be invoiced for this variation
- Currently, a major licence variation fee is \$5,500

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- Change licence holder business name
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Licence Variation Type 3 (\$1,981 each):

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Licence Variation Type 4 (\$11,026):

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Permit Variation Type 1 (\$570 each):

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Proposed New Fees and Charges

Licence Holder Profiles

- Six common Licence Holder profiles are detailed in the Consultation Paper
- Each example profile reflects what the Licence Holder will at a minimum be charged in 2023
- Profiles have three sections
 - Profile diagram – outlining definitive costs
 - Proposed fees and charges that apply to the profile
 - Relevant notes outlining the cost for variations and inspections if required

Existing Licence holder authorised for Cultivation and Production (C&P) activities - with subsequent permit

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    graph TD
      A[Medicinal Cannabis Licence] --> B[Authorising 1 site for:]
      B --> C[Cultivation]
      B --> D[Production]
      C --- E[Site 1]
      D --- E
      E --- F[Cultivation and Production (C&P) Permit]
    
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Profile Specific fees and charges to expect 2023:

Type of fee/charge	Baseline costs
Annual licence charge	\$26,559
Licence variation fees	if required ¹
Subsequent C&P permit application fee	\$8,375
Permit variation fees	if required ²
Inspection	when required ³
Total	\$34,934

¹ If a licence variation application is submitted, a fee of \$534, \$1,357, \$1,981, or \$11,026 applies, depending on the variation type.

² If a permit variation application is submitted, a fee of \$570, or \$1,530, or \$4,743 would apply, depending on the type of variation.

³ When an inspection is required, an application-based inspection amount of \$8,932, or a routine/ongoing inspection amount of \$12,064, or a verification inspection amount of \$4,544 would apply, depending on the reason for inspection.

Proposed New Fees and Charges Options

Option 1 No Increase in fees and charges

Advantages

- No increase in fees and charges for Industry.

Disadvantages

- Will result in under recovery of regulatory costs.
- Inconsistent with Government policy.
- Reduced revenues may require ODC to reduce staffing and services.
- Potential delays in application and permit timelines.
- Will require a revised Government decision to freeze prices.

Option 2 (preferred) Increase in fees and charges linked to increase regulatory costs

Advantages

- Consistent with AGCF that fees and charges set to reflect the minimum efficient cost.
- Consistent with previous Government decisions to cost recover.
- A reduction in regulatory costs would result in reduction of fees and charges.
- Changes to fees and charges occur on an annual basis, as necessary.

Disadvantages

- Increase in some fees and charges, however overall cost impost is lower.

Option 3 Increase in fees and charges linked to annual CPI

Advantages

- Fees and charges would be increased by CPI each year.
- Standard CPI increase efficient to administer.

Disadvantages

- Increases may not align to increases in regulatory costs.
- May result in either over or under recovery.
- Could be inconsistent with the AGCF.
- Will require a revised Government decision to set prices via CPI.

Consultation and Implementation Timeline



Date	Event
19 December 2022	Consultation Commences and Consultation Paper Published
20 December 2022	Public Information Session (Webinar #1)
Late January 2023	Public Information Session (Webinar #2)
10 February 2023	Closing Date for Consultation Period and Submissions
March 2023	Consolidate and finalise feedback
April 2023	Relevant amendments made to regulations
01 July 2023	Cost Recovery Implementation Statement published
01 July 2023	Proposed commencement of revised Fees and Charges

Contact us

Medicinal Cannabis Section

MCS.application@health.gov.au

Further Questions and Information

- Consultation Paper: Medicinal Cannabis Program Regulatory Fees and Charges Review

- Outlines the changes to Fees And Charges
- Available on the ODC consultations hub webpage

<https://consultations.tga.gov.au/tga/medicinal-cannabis-program-fees-and-charges-review/>

- Submissions requirements

- Include Cover Page – found at Attachment A of the Consultation Paper and submit to MCS.application@health.gov.au
- Submissions uploaded via the online survey in the consultation hub at <https://consultations.tga.gov.au/tga/medicinal-cannabis-program-fees-and-charges-review/>
- Must be received by 5pm (EDST) on the 10 February 2022

- Answers to frequently asked questions will be posted on the ODC website

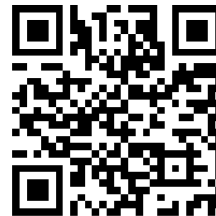
- Enquiries can be sent to MCS.application@health.gov.au.

Survey - Poll

How did we go?

We'll be back with you in **1 minute**.

1. Please open **SLIDO** (*located from your APPS icon*)
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A



Anonymous or Open responses welcome

Questions



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Q&A



Australian Government

Department of Health and Aged Care Office of Drug Control

