Australian Government
Department of Health and Aged Care

COST RECOVERY IMPLEMENTATION STATEMENT

Approval process for pharmacists seeking approval to provide Pharmaceutical Benefits Scheme medicines

2024-25

Charging for regulatory activity involves government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific government activity. The Cost Recovery Policy along with the Australian Government Charging Framework (the Charging Framework) sets out the policy under which government entities design, implement and review charging for regulatory activities. The CRIS is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

Contents

1. INTRODUCTION

1.1. Purpose

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health and Aged Care (the department) implements cost recovery for the process for pharmacists seeking approval to provide pharmaceutical benefits from pharmacy premises. It reports actual financial and non-financial performance information for the pharmacy approval process and contains financial and demand forecasts for 2024-25 and three forward years. The department will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

The approval of pharmacists to supply pharmaceutical benefits is legislated under the *National Health Act 1953* (the Act). Section 90 of the Act provides that the Secretary may, upon application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, approve that pharmacist for the purpose of supplying pharmaceutical benefits at those premises.

An application under section 90 must be referred to the Australian Community Pharmacy Authority (the Authority) unless the application is for the change of ownership of a pharmacy and the pharmacy is to continue to operate at the same premises.

The Authority is a statutory authority established under section 99J of the Act, to consider applications against the requirements of the Pharmacy Location Rules (the Rules) made by the Minister for Health and Aged Care under section 99L of the Act, currently the National Health (Australian Community Pharmacy Authority Rules) Determination 2018.

Cost recovery applies to pharmacists seeking to establish a new pharmacy or relocate an existing pharmacy approved to supply pharmaceutical benefits, and pharmacists wishing to change ownership of a pharmacy or expand or contract the size of a pharmacy premises. Cost recovery consists of application fees to recover the costs for the processes.

Consistent with the Australian Government Charging Framework (the Charging Framework), applicants are charged an application fee as they create the need for the regulatory activity by seeking approval to supply pharmaceutical benefits from a pharmacy premises. Applicants lodging their application are required to pay the application fee at the time they submit their application.

2. POLICY AND STATUTORY AUTHORITY TO CHARGE (COST RECOVER)

2.1. Government policy approval to charge for this regulatory activity

The Government announced the decision to fully recover costs for the pharmacy approval process in the 2018-19 Federal Budget. The measure “Improving Access to Medicines – Sustainability of the pharmacy approval process” included the transfer of pharmacy approvals function from the then Department of Human Services to the department, the development of an IT portal to accept applications, and full cost recovery in the form of application fees.

2.2. Statutory authority to charge

Amendments to section 90 of the Act were made to enable cost recovery to commence. These amendments came into effect on 2 December 2019, allowing for the Minister to determine the fees by legislative instrument. The National Health (Application Fees for Pharmacist Approvals) Determination 2020 (the Determination), setting out the fees, came into effect on 1 July 2020.

3. CHARGING (COST RECOVERY) MODEL

3.1. Outputs and business processes of the activity

The objective of this regulatory charging activity is to improve the efficiency, productivity and responsiveness of the pharmacy approval process and accountability of the submission of pharmacy approval applications. Pharmacists must apply for approval in four different scenarios:

- establishment of a new pharmacy
- relocation of an existing pharmacy approved to supply pharmaceutical benefits
- change of ownership of a pharmacy currently approved to supply pharmaceutical benefits
- expansion or contraction of a pharmacy currently approved to supply pharmaceutical benefits.

Establishment of a new pharmacy and relocation of an existing pharmacy

Approval must be sought from the delegate of the Secretary, via the pharmacy approvals process, before a new pharmacy or a relocated pharmacy can provide pharmaceutical benefits at new premises. Applications for new or relocating pharmacies are assessed by the Authority against the Rules. Subsequently, the Authority makes a recommendation to the delegate before the delegate makes a decision.

The applications requiring involvement of the Authority (i.e. new and relocated pharmacies) are classified as "complex" applications.

The key business processes are:

- receipt, validation, and registration of applications
- consultation with third parties for 'new' pharmacy applications
- provision of applications to members of the Authority for assessment
- provision of secretariat support to the Authority, both before and after the relevant meeting and through attendance at the meeting
- provision of notifications of decisions and reasons for decisions to applicants.

Change of Ownership and Expansion or Contraction of an existing pharmacy

Approval must also be sought from the delegate of the Secretary, via the pharmacy approvals process, where a pharmacist wishes to sell or transfer ownership of their pharmacy (without relocation), or where a pharmacist wishes to change the size of an existing pharmacy premises. However, these applications are not required to be referred to the Authority and are not assessed against the requirements of the Rules.

These applications are classified as "simple" applications.

The key business processes are:

- receipt, validation, and registration of applications
- assessment of the application
- provision of notifications of decisions and reasons for decisions to applicants.

3.2. Costs of the regulatory activity

The approach used to determine the costs of this regulatory charging activity is an Activity-Based Costing (ABC) methodology for the allocation of all direct and indirect costs to the pharmacy approval activities. Direct and indirect costs have been estimated based on the average time required to assess one application. Direct costs are those costs that can be directly attributed to the regulatory charging activity, such as staffing costs. Indirect costs are those costs which are difficult to link to individual activities, such as corporate overhead costs. All indirect costs have been disaggregated and spread throughout the model to provide the full cost of each activity, on the basis of full-time staff equivalents involved in the activity.

Other costs of the activity are delivered by the Authority, which makes recommendations on the complex applications. These costs include sitting and preparation fees as determined by the Remuneration Tribunal. While costs previously included travel and accommodation, travel restrictions and lockdowns resulting from COVID-19, and a reduction in the number of applications requiring considering by the Authority, have led to meetings being conducted online. This will be revisited if there is an operational need to meet face to face.

The 2018-19 Federal Budget provided capital funding to implement a new IT system, which will be cost recovered as depreciation over the useful life of the asset. The depreciation expense is included in table 1 (under the heading 'Capital') and table 5 at section 6.2.

A review of fees is undertaken on an annual basis which consists of assessing the cost of the activities and applying indexation. The review of costs and volumes for the 2024-25 financial year resulted in a reduction of 7.5% to the application fee for simple applications. Accordingly, the fee was reduced from $600 to $555 from 1 July 2024. There was no change to the application fee of $1,600 for complex applications.

Table 1: Estimated Cost per Submission 2024-25

Submissions	Direct Costs	Indirect Costs	Capital	Total
Activity 1 - Simple Submissions				
Direct and Indirect Costs				
Accept, Register & Check Application	$21	$6		$27
Assess Application	$59	$17		$76
Notifications and Correspondences	$64	$19		$83
	$144	**$43**		**$186**
Portal Depreciation Cost			$308	$308
Supplier Costs		$63		$63
Total Cost for Simple Submissions:	**$144**	**$106**	**$308**	**$557**
Activity 2 - Complex Submissions				
Direct and Indirect Costs				
Accept, Register & Check Application	$78	$24		$102
Assess Application	$114	$32		$146
Notifications and Correspondences	$64	$18		$82
ACPA Secretariat - Pre & Post	$169	$44		$213
	$425	**$118**		**$543**
Portal Depreciation Cost			$535	$535
Supplier Costs		$117		$117
ACPA Meeting Costs		$401		$401
Total for Complex Submissions:	**$425**	**$636**	**$535**	**$1,596**

The department will review its administrative processes and forecast volume of applications each year in order to estimate the cost of the regulatory charging activity for the next financial year.

3.3. Design of the regulatory charge

The cost recovery fees are defined by application category and are set out in the Determination. The fee category descriptions are as follows:

Pharmacy Approval Fee Category Description

Application Category	Description
New pharmacy – complex	This is an application that seeks approval for an applicant pharmacist to supply pharmaceutical benefits from a new pharmacy premises. Reviews and assessments by the Authority are required for these applications. This adds an element of complexity to the process. As a result, this application falls under the "complex" category.

Application Category	Description
Relocation – complex	This is an application that seeks approval for an applicant pharmacist to provide pharmaceutical benefits at new pharmacy premises by relocation of a pharmacy already approved to supply pharmaceutical benefits. Reviews and assessments by the Authority are required for these applications. This adds an element of complexity to the process. As a result, this application falls under the "complex" category. The level of processing effort required is the same as establishing a new pharmacy.
Change of ownership – simple	This is an application that seeks approval for an applicant pharmacist by changing ownership of a pharmacy already approved to supply pharmaceutical benefits. These applications do not require assessment by the Authority.
Expansion/Contraction – simple	This is an application that seeks approval for an applicant pharmacist to expand or contract their pharmacy premises at which they are approved to supply pharmaceutical benefits. These applications do not require assessment by the Authority.

Table 2: Charging Category

Charging Category	Type	Unit cost	Unit price	Estimated volume	Estimated total cost	Estimated total revenue
Simple	Fee	$557	$555	490	$272,999	$271,950
Complex	Fee	$1,596	1,600	234	$373,540	$374,400
Total - Fee Paying					**$646,539**	**$646,350**

4. RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken in March 2024 which resulted in a low risk rating.

5. STAKEHOLDER ENGAGEMENT

This cost recovery proposal was initially proposed by the Guild in 2016 due to the issue of applications with little prospect of approval being submitted.

The department considered the proposal and consulted with the Department of Finance to ensure compliance with the Charging Framework.

Following the announcement of the introduction of cost recovery for pharmacy approvals in the 2018-19 Federal Budget, the department engaged with industry in August 2018 to discuss any concerns or suggestions regarding the implementation of cost recovery arrangements. Industry stakeholders that were represented included the Guild, the Pharmaceutical Society of Australia and the Australian Friendly Societies Pharmacies Association. The industry stakeholders acknowledged and supported the introduction of cost recovery application fees.

In accordance with the Charging Framework, the CRIS is to be reviewed and updated at least annually. Formal consultation was not considered necessary for the 2023-24 review, as no changes were made to the charging model, and there were no changes to the fees in 2023-24.

Stakeholders were advised of the 2024-25 review and of its outcome. As the review resulted in the reduction of the fee for simple applications, and no change to the fee for complex applications, there were no sensitivities requiring further formal stakeholder consultation. However, feedback on this CRIS is welcomed by emailing pbsapprovedsuppliers@health.gov.au.

6. FINANCIAL PERFORMANCE

6.1. Financial Estimates

Table 3: Financial estimates

Financial estimates	2024-25 $'000	2025-26 $'000	2026-27 $'000	2027-28 $'000
Total Revenue	$646	$656	$665	$673
Total expenses	$669	$679	$688	$698
Balance (revenue - expense)	-$22	-$23	-$23	-$25
Cumulative balance	$69	$45	$23	-$2

The figures in the table above are forward estimates. Please see section 6.2 for actual financial performance figures.

Any material variance (that is, greater than 5%) will be identified and used to determine the department's balance management strategy. For example, the department may vary the application fee to bring the balance within tolerance levels.

Cost recovery fees are charged on a per submission basis. Actual revenue may vary in line with the fluctuations in the actual volume and type of submissions lodged.

6.2. Financial Outcomes

Table 4: Financial Outcomes

Financial outcomes	2020-21 $'000	2021-22 $'000	2022-23 $'000	2023-24 $'000
Estimates				
Revenue (X)	$2,337	$1,165	$628	$631
Expenses (Y)	$2,519	$1,163	$649	$651
Balance (X-Y)	-$182	$2	-$21	-$20
Actuals				
Revenue (X)	$1,029	$1,252	$780	$726
Expenses (Y)	$1,180	$1,177	$654	$684
Balance (X-Y)	-$151	$74	$126	$42
Cumulative balance	-$151	-$77	$49	$91

The number of applications received is a significant driver of revenue and expenses. In 2023-24 actual revenue and expenses were higher than the estimates as a result of a higher than anticipated number of applications received.

The financial performance of this program is reviewed annually with the aim to achieve alignment between revenue and expenses within a variance of 5%. The cumulative balance of $91,000 represents a variance of less than 2% of the cumulative revenue (and expenses) for the financial years 2020-21 to 2023-24.

Table 5: Depreciation

Depreciation	2024-25 $'000	2025-26 $'000	2026-27 $'000	2027-28 $'000
Net book value - start of financial year	$1,564	$1,288	$1,012	$736
Accumulated Depreciation	$1,086	$1,362	$1,638	$1,914
Depreciation Expense	$276	$276	$276	$276

7. NON-FINANCIAL PERFORMANCE

We have shown the actual volumes of applications received over the 4 years since the fees were introduced, the average for those years, and forecast figures for the current financial year and forward years.

Volumes	Actual				Forecast			
	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28
Simple	425	532	513	524	490	490	490	490
Complex	223	225	254	257	234	234	234	234

The volumes for these applications are variable, and they are expected to fluctuate between reporting periods. The 'actual' figures reflect the number of applications received and subsequently assessed.

8. KEY FORWARD DATES AND EVENTS

Activity	Information to be included and requirements	Due Date
Annual indexation of fees	Review of fees and apply indexation for 2025-26 financial year	31 March 2025
Update of CRIS for 2025-26	Inclusion of 2025-26 indexed fees and forward estimates	30 June 2025
Update of CRIS	Report on actual financial and non-financial results for 2024-25 financial year	30 November 2025

9. CRIS APPROVAL AND CHANGE REGISTER

Date of change	CRIS change	Approver	Basis for change
November 2024	Update of CRIS results for 2023-24	First Assistant Secretary, Benefits Integrity Division	Reporting financial and non-financial results for 2023-24
April 2024	Agreement to 2024-25 CRIS	a/g First Assistant Secretary, Benefits Integrity Division	Review of fees, financial estimates and narrative
November 2023	Update of CRIS results for 2022-23	a/g First Assistant Secretary, Benefits Integrity Division	Reporting financial and non-financial results for 2022-23
April 2023	Agreement to 2023-24 CRIS	First Assistant Secretary, Benefits Integrity Division	Review of fees, financial estimates and narrative
November 2022	Update of CRIS results for 2021-22	First Assistant Secretary, Benefits Integrity and Digital Health Division	Reporting financial and non-financial results for 2021-22
June 2022	Agreement to 2022-23 CRIS	First Assistant Secretary, Benefits Integrity and Digital Health Division	Update of fees, financial estimates and narrative

Date of change	CRIS change	Approver	Basis for change
November 2021	Update of CRIS results for 2020-21	First Assistant Secretary, Benefits Integrity and Digital Health Division	Reporting financial and non-financial results for 2020-21
June 2021	Agreement to 2021-22 CRIS	Minister for Health	Update of fees
May 2021	Update of CRIS for 2021-22	Secretary, Department of Health	Update of fees, financial estimates and narrative
April 2020	Agreement to the CRIS	Minister for Health	New regulatory charging activity
March 2020	Certification of the CRIS	Secretary, Department of Health	New regulatory charging activity