Australian Government

Department of Health and Aged Care

COST RECOVERY IMPLEMENTATION STATEMENT

Approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines 2022-23

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination. 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 CRGs are available on the Department of Finance website (Cost Recovery Guidelines)

1 INTRODUCTION

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health and Aged Care (department) implements cost recovery for the approval process for pharmacists seeking to provide pharmaceutical benefits to Australians. It also reports financial and non-financial performance information for the pharmacy approval process and contains financial forecasts for 2022-23 and three forward years. The department will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

1.2 Description of the regulatory charging activity

1.2.1 Background

The approval of pharmacists to supply pharmaceutical benefits is legislated under the *National Health Act 1953* (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 (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 (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.

The Rules are consistent with the overall objective of the National Medicines Policy to improve the health outcomes of all Australians through access to and quality use of medicines.

A measure in the 2018-2019 Federal Budget to streamline the pharmacy approval process, “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.

1.2.2 Activity being cost recovered

The 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. The cost recovery is in the form of an application fee to recover the costs for the process.

1.2.3 Appropriateness of cost recovery

Consistent with the Australian Government Charging Framework (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 COST RECOVER

2.1 Government policy approval to cost recover the regulatory activity

The Government announced the decision to fully recover costs for the pharmacy approval process in the 2018-19 Federal Budget.

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 *(*Determination), setting out the fees, came into effect on 1 July 2020.

3 COST RECOVERY MODEL

3.1 Outputs and business processes of the regulatory charging 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.

3.1.1 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.

3.1.2 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.

3.1.3 Outputs

The key assumptions used in determining the outputs are:

Measurable Business Processes	**Volume**
Volume of complex applications per year	235
Volume of simple applications per year	420
Number of Australian Community Pharmacy Authority meetings per year	10

3.2 Costs of the regulatory charging 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.

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 amount being recovered for depreciation is based on actual expenditure (previous figures were estimates) as the second phase of IT development has been completed.

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.

As the regulatory charging model had been in place for 12 months, fees charged for the 2021-22 financial year were based on an estimate determined from forecast volumes and the regulatory costing model carried over from the previous financial period and applied to both simple and complex applications.

Amendments to correct any errors or oversights have been applied. A detailed time and motion study was undertaken during the 2021-22 financial year in order to better inform the regulatory charging model to be implemented for the 2022-23 financial year.

Taking into consideration the direct costs, indirect costs, and assumptions, the results of the cost estimates are below.

Estimated Cost per Submission 2022-23	Direct Costs ($)	Indirect Costs ($)	Capital ($)	Total ($)
Activity 1 – Simple Submissions				
Direct and Indirect Costs				
Accept, Register and Check Application	19	6		25
Assess Submission	55	15		70
Notifications and Correspondences	59	17		76
	133	**38**		**171**
Portal Depreciation Cost			333	333
Supplier Costs		96		96
Total Cost for Simple Submissions	**133**	**134**	**333**	**600**
Activity 2 – Complex Submissions				
Direct and Indirect Costs				
Accept, Register and Check Application	72	21		93
Assess Submission	105	29		134
ACPA Secretariat – Pre and Post	156	40		196
Notifications and Correspondences	59	17		76
	393	**107**		**500**
Portal Depreciation Cost			580	580
Supplier Costs		156		156
Authority Meeting Costs		366		366
Total Cost for Complex Submissions:	**393**	**629**	**580**	**1602**

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

4 Design of regulatory charges

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

4.1.1 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.
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.

Charge	Type	Rate	Estimated Volume	Estimated Total Revenue	Output	Business Process
Simple	Fee	$600	420	$252,000	Approve change of pharmacy ownership	Accept, register & check application Assess application

Charge	Type	Rate	Estimated Volume	Estimated Total Revenue	Output	Business Process
					Approve expansion or contraction of an approved pharmacy	Notifications & correspondences
Complex	Fee	$1,600	235	$376,000	Approve new pharmacy Approve relocation of pharmacy	Accept, register & check application Assess application Provide secretariat services to the Authority meeting Notifications & correspondences

The fees being charged for 2022-23 are $600 for simple applications and $1,600 for complex applications. These fees were introduced on 1 August 2022.

5 RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken for the revised model in April 2022, with an overall risk rating of 'medium'. This was due to the CRA having one 'high' rating due to the proposed revised fee for 2022-23 having a greater than 10% variation (reduction) from the previous fee.

6 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. The department notified industry of the 2022-23 review, explaining the process and timing. However more formal consultation was not considered necessary, as while significant changes were made to the costing model, these better reflect the effective cost of the process.

7 FINANCIAL ESTIMATES

Forecast Financial Estimates	2022-23	2023-24	2024-25	2025-26
Combined Expenses = X	$649,090	$655,058	$661,879	$668,438
Combined Revenue = Y	$628,000	$634,800	$641,600	$648,400
Balance = X - Y	-$21,090	-$20,258	-$20,279	-$20,038
Cumulative Balance	-$97,915	-$118,173	-$138,452	-$158,490

The figures in the table above are forward estimates. Please see section 8A for actual financial performance figures for 2020-21.

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.

8 PERFORMANCE

8.1 Financial Performance

The actual financial results for 2021-22 show slightly higher than predicted revenue and expenses as a result of a higher number of simple applications being received in this period. The numbers of applications received are variable and can change significantly from month to month, so this may contribute to future variances.

The following table will be updated after each financial year to report on actual financial performance.

Any year where there is a significant variance, an explanation will be provided.

Actual Financial Performance	2020-21	2021-22	N/A	N/A	N/A
Combined Expenses = X	$1,179,932	$1,177,273			
Combined Revenue = Y	$1,028,780	$1,251,600			
Balance = Y – X	-$151,152	$74,327			
Cumulative balance	-$151,152	-$76,825			
Variance Explanation	2021-22: The forecast revenue for 2021-22 was $1.165 million and the forecast expenses were $1.163 million. Both revenue and expenses were higher as a result of a higher than anticipated number of simple applications received. The number of applications received is a significant driver of revenue and expenses.				
Balance management strategy	2021-22: The cumulative deficit of $76,825 relates to the deficit incurred in 2020-21 which was funded within the department.				

8.2 Non-financial Performance

The department has monitored elements of the activity for pharmacy approval. Initial monitoring was expected to show a reduction in duplicate applications and incomplete applications. The introduction of fees was expected to lead to some improvement in the efficiency, productivity and responsiveness of the pharmacy approval process and accountability of the submission of pharmacy approval applications. To determine whether improvements had been realised, the department initially committed to measuring:

- number of approved applications
  - complex
  - simple
- number of rejected applications
  - complex
  - simple
- processing time of applications
  - complex
  - simple

However, it was noted during the assessment process that the team were conducting identical assessments on all applications, regardless of whether they were ultimately rejected or not. Applications are also sent back to the applicants with requests for further information if the application is incomplete, or the details are not consistent, therefore this was not a good summary of the work that was being carried out.

Instead, we have shown a comparison of the forecast figures of numbers of applications after the fees were introduced, compared with the actual figures. Historically the number of complex applications received each year was reasonably consistent and significantly less than the number of simple applications received. Therefore it is easier to forecast the approximate number of complex applications that will be received in a financial year, with the number of complex applications received in 2021-22 nearly identical to the forecast. It is more difficult to forecast or predict the number of simple applications that will be made in a period, with more variance in the numbers of applications received. The number of simple applications received in 2021-22 was higher than the forecast volumes, which is not unusual or unexpected.

It should be noted that the processing time for nearly 100 percent of applications falls well within the published processing timeframes, and that KPIs for processing are met nearly 100 percent of the time, despite the increase in the number of simple applications received. The few outliers have been due to some applications requiring additional assessment or information, changes in administrative processes and IT issues, rather than time management issues.

Future reporting will continue to focus on these elements, i.e. on numbers of applications received and the time taken to process them, as this will give a comprehensive view of the work undertaken in regard to this regulatory activity.

8.2.1 Number of applications received

	Forecast figures 2020-2021	Actual figures 2020-2021	Actual figures 2021-2022
Simple	420	424	540
Complex	235	223	230

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

9 KEY FORWARD DATES AND EVENTS

Activity	Information to be included and requirements	Due Date
Review of cost model	Review of cost model and update for 2023-24 financial year	31 March 2023
Update of CRIS	Inclusion of 2023-24 revised fees and forward estimates	30 June 2023

10 CRIS APPROVAL AND CHANGE REGISTER

Date of Change to CRIS	CRIS change	Approver	Basis for change
November 2022	Update of CRIS results for 2021-22	Daniel McCabe, 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	Daniel McCabe, First Assistant Secretary Benefits Integrity and Digital Health Division	Update of fees, financial estimates and narrative
November 2021	Update of CRIS results for 2020-21	Daniel McCabe, 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