



Australian Government
Department of Health

COST RECOVERY IMPLEMENTATION STATEMENT

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

2021-22

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 (Health) implements cost recovery for the approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines (pharmaceutical benefits) to Australians. It also reports financial and non-financial performance information for the pharmacy approval process and contains financial forecasts for 2021-22 and three forward years. Health will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

1.2 Description of the regulatory charging activity

Background

The pharmacy approvals process is supported by the Pharmacy Location Rules (Rules). The Rules are a component of the *Seventh Community Pharmacy Agreement* between the Commonwealth of Australia (as represented by Health) and the Pharmacy Guild of Australia (Guild). This Agreement commenced on 1 July 2020 and terminates on 30 June 2025.

The current Rules, which took effect on 3 October 2018, were agreed by Health and the Guild and are legislated under the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* made under section 99L of the *National Health Act 1953* (Act).

The Rules remain 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.

In order to streamline the pharmacy approval process, the function was transferred from the then Department of Human Services to Health from January 2019 and an IT system to support business efficiencies for applicants and Health was developed and implemented on 9 October 2019. The IT system has undergone a number of enhancements, the most recent of which was implemented on 25 March 2021.

Full cost recovery in the form of application fees was announced in the 2018-19 Federal Budget, and introduced on 1 July 2020.

Activity being cost recovered

In the 2018-19 Federal Budget, the Government announced that pharmacists seeking to establish a new pharmacy or relocate an existing pharmacy to provide pharmaceutical benefits would be charged a fee to recover the costs for the process. Additionally, costs would be recovered from applicants wishing to change ownership of a pharmacy or expand or contract the size of a pharmacy premises.

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 through the desire 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.

Other stakeholders

A key activity in the pharmacy approval process is one which utilises the Australian Community Pharmacy Authority (the Authority). The Authority is a statutory authority established under section 99J of the Act. The Authority considers applications for approval to supply pharmaceutical benefits under section 90 of the Act, against the requirements of the Rules, and makes recommendations as to whether or not an application should be approved. The Authority is made up of members nominated by the Guild, the Pharmaceutical Society of Australia, consumer organisations and Health, along with an independent Chair.

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. The Act provides for the Minister to determine the fees by legislative instrument. *The National Health (Application Fees for Pharmacist Approvals) Determination 2020* (Determination), setting out the fee amount, 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 providing pharmaceutical benefits
- change of ownership of a pharmacy currently providing pharmaceutical benefits
- expansion or contraction of a pharmacy currently providing 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.

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

The key business processes are:

- accept, register and check the application
- assess the application
- provide secretariat services to the Authority, both before and after the relevant meeting and through attendance at the meeting
- provide notifications and correspondence to applicants.

Change of Ownership and Expansion or Contraction

Pharmacists wishing to sell or transfer ownership of their pharmacy without relocation, and pharmacists wishing to change the size of their pharmacy premises, also require approval by the delegate of the Secretary. However, these applications are not considered by the Authority against the Rules.

Expansion or contraction and change of ownership applications not requiring Authority involvement are classified as “simple” applications.

The key business processes are:

- accept, register and check the application
- assess the application
- provide notifications and explanations to applicants.

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 were 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 will be based on a set amount each year. This is now 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 fees
- preparation fees
- travel costs
- accommodation costs.

These costs are allocated in the Authority meeting costs. The impact of COVID 19 has been considered in determining Authority meeting costs for 2021-22, including a reduction in travel and accommodation costs.

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 and a detailed time and motion study will be undertaken during this 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 result of the cost estimates are below.

Estimated Cost per Submission 2021-22	Direct Costs (\$)	Indirect Costs (\$)	Capital (\$)	Total (\$)
Activity 1 – Simple Submissions				
Direct and Indirect Costs				
Accept, Register and Check Application	38	13		51
Assess Submission	418	125		543
Notifications and Correspondences	77	23		100
	533	161		694
Portal Depreciation Cost			245	245
Supplier Costs		107		107
Total Cost for Simple Submissions	533	268	245	1046
Activity 2 – Complex Submissions				
Direct and Indirect Costs				
Accept, Register and Check Application	144	43		187
Assess Submission	604	165		769
ACPA Secretariat – Pre and Post	441	111		552
Notifications and Correspondences	114	35		149
	1302	354		1656
Portal Depreciation Cost			735	735
Supplier Costs		320		320
Authority Meeting Costs		366		366
Total Cost for Complex Submissions:	1302	1040	735	3078

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.

3.3 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:

Pharmacy Approval Fee Category Description

Application Category	Description
New pharmacy – Complex	<p>This is an application that seeks approval for pharmacists to provide pharmaceutical benefits from a new pharmacy premises.</p> <p>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.</p>
Relocation – Complex	<p>This is an application that seeks approval for pharmacists to provide pharmaceutical benefits from a relocated pharmacy premises.</p> <p>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.</p> <p>The level of processing effort required is the same as establishing a new pharmacy.</p>
Change of ownership – Simple	<p>This is an application that seeks approval for changing ownership of a pharmacy already approved for providing pharmaceutical benefits.</p> <p>These applications do not require assessment by the Authority.</p>
Expansion/Contraction – Simple	<p>This is an application that seeks approval for an applicant pharmacist to expand or contract their approved pharmacy premises which is currently providing pharmaceutical benefits.</p> <p>These applications do not require assessment by the Authority.</p>

Charge	Type	Rate	Estimated Volume	Estimated Total Revenue	Output	Business Process
Simple	Fee	\$1,050	420	\$441,000	Approve change of pharmacy ownership; Approve expansion or contraction of an approved pharmacy	Accept, register & check application; Assess application; Notifications & correspondences.
Complex	Fee	\$3,080	235	\$723,800	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 2021-22 are \$1,050 for simple applications and \$3,080 for complex applications.

4 RISK ASSESSMENT

A charging risk assessment was undertaken in April 2021. The outcome of this risk assessment was an overall risk rating of 'medium'.

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.

Health 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, Health 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. Health has notified industry of the 2021-22 review, explaining the process and timing, however more formal consultation was not considered necessary as major changes were not made to the costing model.

6 FINANCIAL ESTIMATES

Forecast Financial Estimates	2021-22	2022-23	2023-24	2024-25
Combined Expenses = X	\$1,162,907	\$1,172,666	\$1,185,222	\$1,197,995
Combined Revenue = Y	\$1,164,800	\$1,171,850	\$1,187,300	\$1,196,450
Balance = X - Y	\$1,893	-\$816	\$2,078	-\$1,545
Cumulative Balance	-\$149,259	-\$150,075	-\$147,997	-\$149,542

The figures in the table above are forward estimates. Please see section 7A for actual financial performance figures for 2020-21.

Any material variance (that is, greater than 5%) will be identified and used to determine Health's balance management strategy. For example, Health 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.

7 PERFORMANCE

7.1 Financial Performance

The actual financial results show lower than predicted revenue, however the expenses were slightly higher than predicted. The lower revenue is a result of an initial miscalculation of the fees to be charged, which was subsequently corrected. The numbers of applications have also dropped since the initial forecast, contributing to the lower than predicted revenue. 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	N/A	N/A	N/A	N/A
Combined Expenses = X	\$1,179,932				
Combined Revenue = Y	\$1,028,780				
Balance = Y - X	-\$151,152				
Cumulative balance	-\$151,152				
Variance Explanation	The forecast revenue for 2020-21 was \$2.3 million and the forecast expenses were \$2.5 million. The number of applications received is a significant driver of revenue and expenses. Additionally, due to a miscalculation of fees in the initial forecasts, the expected revenue was higher than the actual revenue for 2020-21. This has been corrected and applied and all applicants who paid the				

Actual Financial Performance	2020-21	N/A	N/A	N/A	N/A
	incorrect higher fees have been offered the opportunity to apply for a refund, of which most have been actioned.				
Balance management strategy	The deficit of \$151,152 was funded within the Department of Health. Due to the unique circumstances of this deficit, it is not expected that ongoing deficits will be material in the forward years.				
^a As defined by AASB1031 and Division 12 – Materiality and Disclosure of the Finance Minister’s Orders.					

7.2 Non-financial Performance

Health 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, Health 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. The figures are nearly identical, but whether the predicted reduction in applications was due to the introduction of fees or outside influences such as the impact of covid-19 may need further evaluation.

It should be noted that the team have also ensured that the processing time for nearly 100 percent of applications falls well within the published processing timeframes, and the team is meeting KPIs for processing nearly 100 percent of the time. The few outliers have been due to IT issues, rather than process issues.

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

Number of applications received 2020-21

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

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 by the team.

8 KEY FORWARD DATES AND EVENTS

Activity	Information to be included and requirements	Due Date
Update of 2020-21 Financial Performance	Estimates to be replaced with actual figures	30 November 2021
Review of cost model	Review of cost model and update for 2022-23 financial year	31 March 2022
CRIS update	Fees for 2022-23	30 June 2022
Update CRIS for 2021-22 actual results	Report financial and non-financial information for 2021-22	30 November 2022

9 CRIS APPROVAL AND CHANGE REGISTER

Date of Change to CRIS	CRIS change	Approver	Basis for change
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