Australian Government

Department of Health

COST RECOVERY IMPLEMENTATION STATEMENT

Approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines

2020-21

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 (PBS) medicines to Australians. It also reports financial and non-financial performance information for the pharmacy approval process and contains financial forecasts for 2020-21 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 (the Rules). The Rules are a fundamental component of the Sixth Community Pharmacy Agreement (the Sixth Agreement) between the Commonwealth of Australia (as represented by Health) and the Pharmacy Guild of Australia (the Guild). This Agreement commenced on 1 July 2015 and terminates on 30 June 2020.

The Rules, which took effect on 18 October 2011, were agreed by Health and the Guild, with amendments incorporated for applications made on or after 3 October 2018. The Rules are legislated under the National Health (Australian Community Pharmacy Authority Rules) Determination 2018 made under section 99L of the 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.

Health manages the Rules and the Australian Community Pharmacy Authority (the Authority) which considers pharmacy approval applications and recommendations whether to approve or not to approve the applications. The Authority recommendations are provided to the delegate of the Secretary of the Department of Health who grants the final approval. Once approval is given, the pharmacist is able to provide PBS medicines under section 90 of the *National Health Act 1953 (the Act)*.

In order to streamline the pharmacy approval process, the function was transferred from the then Department of Human Services (DHS) to Health. An investment in technology is being developed to support efficiencies. The first phase of the IT portal was introduced in October 2019 with the full functionality scheduled to be implemented by July 2020.

There was a delay in the commencement of the pharmacy approvals cost recovery measure from the date announced in the 2018 Budget, 1 July 2019, as the introduction and passage of the associated Bill was delayed due to the prorogation of Parliament and subsequent 2019 Federal Election.

Activity being cost recovered

In the 2018 Budget the Government announced that pharmacists seeking to establish a new pharmacy or relocate an existing pharmacy to provide PBS medicines will be charged a fee to recover the costs for the process. Additionally, costs will be recovered from applicants wishing to change ownership of a pharmacy.

Appropriateness of cost recovery

Consistent with the Australian Government Charging Framework (the Charging Framework), applicant pharmacists will be charged an application fee as they create the need for the regulatory activity through the desire to supply PBS medicines from a pharmacy premises. Applicants lodging their application will be required to pay the application fee at the time they submit their application. Further reviews and consultations will cover requirements of future processes and, additionally, a time and motion study of the future processes will occur within the first twelve months of the implementation of these cost recovery arrangements.

Other stakeholders

A key activity in the pharmacy approval process is one which utilises 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 representing the Guild, the Pharmaceutical Society of Australia, consumers 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

In the 2018 Budget, the Government announced the decision to fully recover costs for the pharmacy approval process, commencing on 1 July 2019. This measure also included transferring the administrative responsibility of pharmacy approvals from DHS to Health. This transfer of responsibility was to streamline the pharmacy approvals process as all application and approval processing would be undertaken by Health.

As a result of the delays previously mentioned, the recovery of costs will commence on 1 July 2020.

2.2 Statutory authority to charge

Amendments to Section 90 of the *National Health Act 1953* were made to enable cost recovery to commence. These amendments came into effect on 2 December 2019. A legislative instrument setting out the cost recovery fees is also required to be made before charging can commence.

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. The pharmacy approval applications must comply with the Rules. Pharmacists must apply for approval in four different scenarios:

- The establishment of a new pharmacy;
- The relocation of an existing pharmacy providing PBS medicines;

- The change of ownership of a pharmacy currently providing PBS medicines; and
- Expansion or contraction of a pharmacy.

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 PBS subsidised medicines 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 submission;
- Provide secretariat services to the Authority, both before and after the relevant meeting and through attendance at the meeting; and
- Provide notifications and explanations to applicants.

Change of Ownership and Expansion or Contraction

Pharmacists wishing to sell or transfer ownership of their pharmacy without relocation 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 submission; and
- Provide notifications and explanations to applicants.

The key assumptions used in determining the outputs are:

Volume of complex applications per year	341
Volume of simple applications per year	490
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 Budget provided capital funding to implement new IT technology 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.

Other costs of the activity are delivered by the supplier, the Authority, which makes recommendations on the complex applications. These costs include:

- Sitting fees;
- Preparation fees;
- Travel costs; and
- Accommodation costs.

These costs are allocated in the Authority meeting costs.

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

Estimated Cost per Submission 2020-21	Direct Costs	Indirect Costs	Capital	Total
Activity 1 - Simple Submissions				
Direct and Indirect Costs				
Accept, Register & Check Application	$38	$13		$51
Assess Submission	$414	$125		$539
Notifications and Correspondences	$76	$23		$ 99
	$528	$161		$689
Portal Depreciation Cost			$159	$ 159
Online Portal Operational cost		$66		$66
Total Cost for Simple Submissions:	$528	$227	$ 159	$914
Activity 2 - Complex Submissions				
Direct and Indirect Costs				
Accept, Register & Check Application	$142	$43		$185
Assess Submissions	$597	$165		$762
ACPA Secretariat - Pre & Post	$1,505	$409		$1,914
Notifications and Correspondences	$1,545	$401		$1,946
	$3,790	$1,018		$4,808
Portal Depreciation Cost			$478	$478
Online Portal Operational cost		$198		$198
ACPA Meeting Costs		$589		$589
Total for Complex Submissions:	$3,790	$1,805	$478	$6,073

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 will be set out in the *National Health (application fee – pharmacy approvals) Determination* 2020. 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 pharmacists to provide PBS medicines 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 pharmacists to provide PBS medicines from a relocated 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. The level of processing effort required is the same as establishing a new pharmacy.
Change of ownership – Simple	A simple application seeks approval for changing ownership of a pharmacy already approved for providing PBS medicines. These applications do not require significant amounts of processing or assessment by the Authority.
Expansion/Contraction – Simple	This application seeks approval for an applicant pharmacist to expand or contract their approved pharmacy premises. These applications do not require significant amounts of processing or assessment by the Authority.

Charge	Type	Rate	Estimated Volume	Estimated Total Revenue	Output	Business Process
Simple	Fee	$920	490	$450,800	Approve change of pharmacy ownership; Approve expansion or contraction of an approved pharmacy	Receive application; Assess submission; Notify applicant.
Complex	Fee	$5,530	341	$1,885,730	Approve relocation of pharmacy; Approve new pharmacy.	Receive application; Assess submission; Provide secretariat services to the Authority meeting; Notify applicant and explain decision.

The fees charged for providing this service were agreed as part of the stakeholder consultation undertaken in 2018 with the expectation that cost recovery arrangements would be implemented from 1 July 2019. Although implementation has been delayed to 1 July 2020, the fees being charged for the 2020-21 financial years will remain at $920 for simple applications and $5,530 for complex applications.

4. RISK ASSESSMENT

Being a new regulatory charging activity for Health, there is a risk that the cost estimates are inaccurate. Health has managed this risk by considering the costs of comparable activities that it undertakes. Processes and cost estimates will be reviewed each year and adjusted if required.

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 Budget, Health engaged with industry on 13 August 2018 to discuss any concerns or suggestions regarding the implementation of cost recovery arrangements. Industry stakeholders that were engaged included members from the Guild, the Pharmaceutical Society of Australia and the Australian Friendly Societies Pharmacies Association. After the engagement, feedback was provided to Health during a consultation period and considered in preparing this CRIS. As a result, industry stakeholders acknowledged and supported the details of the budget measure which includes the introduction of cost recovery application fees.

In accordance with the Charging Framework, the CRIS will be updated annually. It is anticipated that the volume, costs and associated cost recovery revenue will be reviewed after the IT system implementation in 2020-21. The functionality of the IT system will impact upon the outcome of this review and will be reflected in the CRIS for 2021-22.

6. FINANCIAL ESTIMATES

Forecast Financial Estimates	2020-21	2021-22	2022-23	2023-24
Expenses = X	$ 2,518,886	$ 2,556,108	$ 2,595,774	$ 2,634,103
Revenue = Y	$ 2,336,530	$ 2,599,100	$ 2,677,100	$ 2,716,100
Balance = Y - X	-$ 182,356	$ 42,992	$ 81,326	$ 81,997
Cumulative Balance	-$ 182,356	-$ 139,364	-$ 58,038	$ 23,959

The figures in the table above are forward estimates. A review of actual financial performance compared to estimates will be undertaken annually.

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. NON-FINANCIAL PERFORMANCE

Health will be monitoring the activity for pharmacy approval applications with an expectation of a reduction in duplicate applications and incomplete applications. By charging fees, it is expected this will improve the efficiency, productivity and responsiveness of the pharmacy approval process and accountability of the submission of pharmacy approval applications. To determine the performance, Health will be measuring:

- No. of approved applications
    - Complex
    - Simple
- No. of rejected applications
    - Complex
    - Simple
- Processing time of applications
    - Complex
    - Simple

8. KEY FORWARD DATES AND EVENTS

- 1 July 2020 – Introduction of cost recovery for pharmacy approval applications
- March 2021 – Review cost recovery arrangements prior to 2021-22 CRIS being updated.

9. CRIS APPROVAL AND CHANGE REGISTER

Date of Change to CRIS	CRIS change	Approver	Basis for change
30/03/2020	Certification of the CRIS	Secretary, Department of Health	New regulatory charging activity
24/04/2020	Agreement to the CRIS	Minister for Health	New regulatory charging activity