

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health and Aged Care

National Health Act 1953

National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2022

The *National Health Act 1953* (the Act) makes provision in relation to pharmaceutical, sickness and hospital benefits, and medical and dental services.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted or are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Act enables fees to be charged to recover the costs of certain services provided by the Commonwealth. Under the Act, payment of fees may be required for services that relate to the exercise of a power by the Minister under the following provisions:

- Section 9B of the Act. This section sets out that the Minister may provide, or arrange for the provision of, designated vaccines and goods and services associated with or incidental to the provision or administration of designated vaccines. Services provided by the Commonwealth in relation to this section include those provided in connection with the National Immunisation Program (NIP), including activities of the Australian Technical Advisory Group on Immunisation (ATAGI) and the Pharmaceutical Benefits Advisory Committee (PBAC).
- Part VII of the Act. This part deals with matters related to the supply of and payments for pharmaceutical benefits and the Pharmaceutical Benefits Scheme (PBS). Services provided by the Commonwealth in relation to this part include the administration of the PBS, activities of the PBAC and its sub-committees, and other services carried out by the Department of Health (the Department) to assist the Minister to exercise the relevant powers under Part VII of the Act.

The Act provides for regulations to set out the fees that are payable and manner of payment for those services. A prescribed fee is payable to the Commonwealth and must not be such as to amount to taxation. The Act allows the regulations to set out other matters including the making of applications, exemptions from prescribed fees, the waiver, remission or refund of prescribed fees, the consequences of late payment or failing to pay a fee, and the review of decisions made under the regulations. A consequence of failing to pay a fee is that the Minister may refuse to exercise certain powers under the Act until the fee is paid.

Purpose

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2022* (the Principal Regulations) prescribe fees and matters relating to the making of applications or submissions for services provided by the Commonwealth in relation to the exercise of certain powers by the Minister under the Act.

The Department assesses the cost effectiveness of vaccines for inclusion on the NIP as well as drugs for listing on the PBS. Much of the assessment work is carried out by external evaluators at a cost to Government. The Principal Regulations implement cost recovery arrangements whereby these evaluation costs are recouped from the pharmaceutical industry through fees.

The purpose of the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2022* (the Amendment Regulations) is to:

- update cost recovery fees for the 2022-23 financial year in relation to applications for listing on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP);
- amend the wording of Regulation 51(2) to ensure that withdrawal of a pricing application within the specified timeframe results in a refund of the fee paid;
- amend the wording of Regulation 51(4) to ensure that withdrawal of pricing applications after the specified timeframe results in the provision of the appropriate refund amount; and
- include new transitional provisions to ensure that any pricing applications received since 1 April 2022 and withdrawn outside of the specified timeframe are provided with the appropriate refund amount.

In line with Australian Government Cost Recovery Guidelines, the Principal Regulations are updated annually to ensure they accurately reflect the efficient costs of providing services.

Details of the operation of the Amendment Regulations are provided in the [Attachment](#).

The Amended Regulations commenced on 1 August 2022.

The Principal Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

A Statement of Compatibility with Human Rights has been completed for the Amendment Regulation, in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*. The Statement's assessment is that the measures in the Amendment Regulations are compatible with human rights.

Consultation

The changes in the amended regulations have been discussed with representatives of the pharmaceutical industry. Public consultation on the draft Cost Recovery Implementation Statement, which advises industry of the fee changes for the 2022-23 financial year, was undertaken in June 2022. The proposed changes were supported by the pharmaceutical industry.

Details of the proposed *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2022*

Section 1 – Name

This section provides that the title of the Regulations is the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2022*.

Section 2 – Commencement

This section provides for the Amendment Regulations to commence on 1 August 2022.

Section 3 – Authority

This section provides that the Amendment Regulations are made under the *National Health Act 1953*.

Section 4 – Schedule(s)

This section provides that each instrument specified in the Schedule is amended or repealed as set out in the applicable items in the Schedule and that any other item in the Schedule has effect according to its terms.

Schedule 1 – Amendments

Item [1] – Subsection 7(2)

This item substitutes the ‘complex category Australian Technical Advisory Group on Immunisation (ATAGI) application fee’ amount within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department of Health (the Department) to recover the cost of providing services in response to a ‘complex’ application for ATAGI advice.

ATAGI provides advice to support the Pharmaceutical Benefits Advisory Committee’s (PBAC’s) evaluation of vaccines for the National Immunisation Program (NIP), including on clinical, technical and implementation matters.

The substituted fee has decreased which, in practice, means that applicants who submit a ‘complex’ ATAGI application, pay a reduced amount compared to the prior financial year. The decrease has been determined following the Department’s annual review of cost recovery fees.

Item [2] – Subsection 7(2)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services by the Department in relation an ATAGI application or the notice of intent for an ATAGI application.

Item [3] – Subsection 8(4)

This item substitutes the ‘simple category’ ATAGI fee amount within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department to cost recover the services provided in response to a ‘simple category’ application for ATAGI advice.

Item [4] – Subsection 8(4)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services by the Department in relation to an ATAGI application or the notice of intent for an ATAGI application.

Item [5] – Subsection 12(4)

This item substitutes the fee payable for the provision of administrative services within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to an ATAGI application or the notice of intent for an ATAGI application.

Items [6] and [7] – Section 14 (table items 1 and 2)

Items 6 and 7 substitutes the fee amounts for a ‘first’ and ‘second’ PBAC presubmission meeting within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

These fees are charged by the Department to recover the cost of holding a presubmission meeting with an applicant to support development of their submission to the PBAC.

Item [8] – Subsection 22(2) (table)

This item substitutes the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application submission services:

- a) for the PBAC to consider making a recommendation that may enable, amend or cease the public funding of a pharmaceutical or vaccine; or
- b) to assist the Minister to determine a brand of pharmaceutical item.

There are six submission categories and four resubmission pathways for submissions to the PBAC.

Submission categories are determined based on the applicant’s request in their submission. With the exception of the standard re-entry pathway, resubmission pathways are nominated

by the PBAC following a ‘not recommended’ PBAC outcome. Applicants nominate their submission category or resubmission pathway via the intent to apply form.

Item [9] – Subsection 22(2) (note 4)

This item substitutes the fee payable for the provision of administrative services within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to a submission or notice of intent for a submission.

Item [10] – Subsection 35(6)

This item substitutes the fee payable for the provision of administrative services within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to a submission or notice of intent for a submission.

Items [11] through [15] – Subsection 41(1) (table items 1 through 5)

These items substitute the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application for pricing services.

There are five different pricing pathways (pricing application categories) to progress a positive PBAC recommendation.

Pricing Pathway A requires the PBAC to recommend that it is appropriate for a submission to follow this pathway. All other pricing pathways are determined based on the listing arrangements required. Applicants nominate their pricing pathway via the Notice of Intent for Pricing form.

Item [16] – Subsection 41(2)

This item substitutes the non-refundable deposit amount within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

Under the Principal Regulations, fees for application services also include a non-refundable deposit amount. This fee is charged by the Department to cost recover administrative services by the Department in relation a pricing application or the notice of intent for a pricing application.

Item [17] – Paragraph 41(3)(a)

This item substitutes the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway A where a deed is not entered into because an applicant withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Item [18] – Paragraph 41(3)(b)

This item substitutes the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway B where a deed is not entered into because an applicant withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Item [19] – Paragraph 41(3)(c)

This item substitutes the refund amount currently provided for within the Principal Regulations relating to the Pricing Pathway C where a deed is not entered into because an applicant withdraws their pricing application or there has been no active negotiation for 26 weeks. Only the rebate management component of the pricing pathway fee is refunded.

Item [20] – At the end of paragraph 51(2)(c)

This item provides that if an applicant withdraws their notice of intent or pricing application under certain circumstances and all or part of the fee for providing pricing services in response to the pricing application was paid before the withdrawal of the notice of intent, the Department will refund the fee amount paid except for the deposit amount outlined in subsection 41(2).

Item [21] – Subsection 51(4)

This item provides that if an applicant withdraws their notice of intent or pricing application after 10 business days from the day the Department issued a notification in response to the notice of the intent or pricing application provided, if the notice of intent or pricing application is in relation to the entering of a deed under section 85E of the Act and all or part of the fee was paid before the withdrawal, the Department must refund the fee amount paid except for the deposit amount outlined in subsection 41(3).

Items [22] – Subsection 51(5)

This item substitutes the fee payable for the provision of administrative services within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

This fee is charged by the Department to cost recover administrative services by the Department in relation to a pricing application or notice of intent for a pricing application.

Items [23] through [26] – Subsection 56(1) (table items 1 through 4)

These items substitute the fee amounts currently provided for within the Principal Regulations to reflect the revised fees for the 2022-23 financial year.

These fees are charged by the Department to recover the costs of the services provided in response to an application for list management services. List management services includes activities that are directly requested by applicants seeking to manage their listing on the PBS.

- List management options include:
- Price increase requests including brand premium requests;
- Ministerial discretion requests;
- Deed renewal requests; and
- Deed variation requests.

Item [27] – Subsection 60(2)

This item substitutes the amount currently provided for within the Principal Regulations which is refunded by the Department where an applicant withdraws their deed renewal application and a deed arrangement has not been entered into.

Item [28] – At the end of the Part 9

This item inserts an application provision to clarify that the revised fees apply to all applications and submissions given on or after 1 August 2022.

The application provision also provides that amendments to subsection 51(4) apply to all pricing applications or notice of intent in relation to a pricing application given and withdrawn on or after 1 August 2022. The amendment was necessary to ensure applicants are receiving appropriate refund amounts. This application provision does not disadvantage applicants that may be subject to amendments to subsection 51(4).

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2022

The *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (Fees) Regulations 2021* (the Amendment Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Regulations

The Amendment Regulations update cost recovery fees for the 2022-23 financial year in relation to applications for listing on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP).

The Amendment Regulations are made under section 140 of the *National Health Act 1953* (the Act). Section 140 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters, which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act. Subsection 99YBA(2) of the Act further provides that regulations may make provision in relation to matters including the prescribing of fees, the making of applications, and exemptions from the prescribed fees, in relation to services provided by the Commonwealth under section 9B or Part VII of the Act.

The Amendment Regulations amend the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022* (the Principal Regulations). The Amendment Regulations provide for fees for services provided by the Commonwealth in relation to an exercise of power by the Minister under section 9B or Part VII of the Act:

- The Minister’s powers under section 9B of the Act broadly relate to the National Immunisation Program (NIP).
- The Minister’s powers under Part VII broadly concern the listing process for applications for pharmaceuticals to be included in the Pharmaceutical Benefits Scheme (PBS).

Human rights implications

The Amendment Regulations engage Article 2 and Article 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS and NIP are benefit schemes, which assist with advancement of this human right by providing patients with subsidised access to medicines. By accurately recovering the costs of assessing applications for subsidy, the Commonwealth ensures that the medicine and vaccine assessment process remains financially sustainable and contributes to a viable and well-functioning PBS. This means that Australians will continue to have access to safe, effective medicines which, in turn, promotes the various rights to health in the Conventions.

Conclusion

This Legislative Instrument is compatible with human rights. Human rights continue to be protected by ensuring the PBS and NIP are financially sustainable and will continue to assess applications for subsidy of medicines and vaccines which benefit the health of Australian citizens.

The Hon Mark Butler MP

Minister for Health and Aged Care