

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2024

PB 48 of 2024

Purpose

The *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2024* (the Instrument) amends the *National Health (Application Fees for Pharmacist Approvals) Determination 2020* (PB 31 of 2020) (the Principal Determination) to change the application fee that must accompany a pharmacist's application for approval to supply pharmaceutical benefits at particular premises under subsections 90(1) or (3) of the *National Health Act 1953* (the Act), where that application is not required to be referred to the Australian Community Pharmacy Authority (the Authority).

Application fees applying from 1 July 2024

Schedule 1 of the Instrument sets out amendments to the application fee in the Principal Determination to take effect from 1 July 2024. For applications that must be referred to the Authority, the fee remains unchanged from \$1,600, while for all other applications, the fee is reduced from \$600 to \$555.

The application fee is being reduced in line with the Department of Health and Aged Care's review of the Cost Recovery Implementation Statement (CRIS), (*Approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines 2024-25*). The reduced application fee reflects the updated costings as determined by the review of the CRIS. The review of the CRIS found that the application fee for an application that is required to be referred to the Authority should remain unchanged.

Background

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to a wide range of medicines.

Under subsections 90(1) or 90(3) of the Act, pharmacists can apply for approval to supply pharmaceutical benefits at particular premises. The Principal Determination sets out the fees for these applications, which are calculated according to the CRIS and reflect the overall costs of the approval process. The charging of application fees is a means of cost-recovery in line with the Australian Government Charging Framework (Charging Framework), which provides that where a specific demand for a government activity is created by identifiable individuals, those individuals should generally bear the costs of that activity.

The CRIS describes the Activity-Based Costing methodology used to determine the costs of this regulatory charging activity. Direct and indirect costs have been estimated based on the average time required to assess one application, with direct costs being those costs that can be attributed to the regulatory charging activity, such as staffing costs, and indirect costs being those costs which are difficult to link to individual activities such as corporate overhead costs.

The Department of Health and Aged Care reviews the CRIS annually, in accordance with the Charging Framework. The 2024-25 review included consideration of the volume of applications, indirect supplier costs, and costs of monthly meetings of the Authority.

Authority

Subsection 90(10) of the Act provides for the Minister to make a legislative instrument to determine the application fees payable under subsection 90(9) of the Act when making applications under subsections 90(1) or 90(3) of the Act to supply pharmaceutical benefits at particular premises. Subsection 90(11) of the Act allows the Minister to determine different fees for different kinds of applications.

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Consultation

In March 2024, the Department of Health and Aged Care communicated with representatives from the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia to inform them that a review of the CRIS was being undertaken and was expected to be finalised by the 30 June 2024, and that the timing of the introduction of revised fees resulting from the review was subject to Ministerial approval. No concerns were raised with the Department.

Commencement

The Instrument commences on 1 July 2024.

General

The Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Instrument are set out in the **Attachment A**.

The Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2024*

Section 1 Name

Section 1 provides that the name of the Instrument is the *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2024*.

The Instrument may also be cited as PB 48 of 2024.

Section 2 Commencement

Section 2 provides that this Instrument commences on 1 July 2024.

Section 3 Authority

Section 3 provides that the Instrument is made under subsection 90(10) of the *National Health Act 1953*.

Section 4 Schedules

Section 4 provides that each instrument that is specified in the Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in the Schedule has effect according to its terms. Schedule 1 amends the *National Health (Application Fees for Pharmacist Approvals) Determination 2020*.

Schedule 1 Amendments

Item 1 – Paragraph 4(b)

Item 1 amends paragraph 4(b) of the *National Health (Application Fees for Pharmacist Approvals) Determination 2020* to reduce the application fee for an application made under subsections 90(1) or 90(3) of the Act in circumstances where the application is not required to be referred to the Australian Community Pharmacy Authority under subsection 90(3A) of the Act. The fee is reduced from \$600 to \$555 to reflect the updated costings as determined by the review of the Cost Recovery Implementation Statement.

The application fee for an application made under subsections 90(1) or 90(3) of the Act where the application must be referred to the Australian Community Pharmacy Authority will remain as \$1,600.

Statement of Compatibility with Human Rights

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

*National Health (Application Fees for Pharmacist Approvals) Amendment Determination
2024*

PB 48 of 2024

The *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2024* (the Instrument) is 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 Instrument

The Instrument amends the *National Health (Application Fees for Pharmacist Approvals) Determination 2020* to reduce the fee for applications made by pharmacists for approval to supply pharmaceutical benefits at particular premises under subsections 90(1) or 90(3) of the *National Health Act 1953* and in circumstances where the application is not required to be referred to the Australian Community Pharmacy Authority. The fee is reduced from \$600 to \$555.

The changes to the fees are based on the Department of Health and Aged Care's annual review of costs associated with processing applications, undertaken in line with the Australian Government Charging Framework.

Human rights implications

This Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing subsidised access to medicines (pharmaceutical benefits) for Australians. It provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. Allowing the Commonwealth to recover its costs associated with the processing of applications for approval to supply pharmaceutical benefits, will improve the efficiency, productivity and responsiveness of the pharmacy approval process. This in turn will assist pharmacists to provide Australians with more timely access to pharmaceutical benefits in areas of demonstrated need. This is a positive step towards attaining the highest standard of health for all Australians, as efficient operational arrangements support effective administration of the PBS.

Conclusion

This Instrument is compatible with human rights as it advances the protection of human rights.

Mark Butler

Minister for Health and Aged Care