

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (APPLICATION FEES FOR PHARMACIST APPROVALS) AMENDMENT DETERMINATION 2022

PB 65 of 2022

Authority

Subsection 90(10) of the *National Health Act 1953* (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 section 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.

Purpose

The *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2022* (the Instrument) amends the *National Health (Application Fees for Pharmacist Approvals) Determination 2020* (PB 31 of 2020) (the Principal Determination) to change the application fees that must accompany an application for approval to supply pharmaceutical benefits at particular premises under subsection 90(1) or (3) of the Act. The Instrument makes prospective amendments to specify the application fees that will apply from 1 August 2022.

Application fees applying from 1 August 2022

Schedule 1 of the Instrument sets out amendments to the application fees in the Principal Determination to take effect from 1 August 2022. For applications that must be referred to the Australian Community Pharmacy Authority (the Authority), the fee is reduced from \$3,080 to \$1,600. For all other applications, the fee is reduced from \$1,050 to \$600.

The application fees are being reduced in line with the Department of Health's review of the Cost Recovery Implementation Statement (CRIS), (*Approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines 2022-23*). The reduced application fees reflect the updated costings as determined by the review of the CRIS.

Background

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS), the Australian Government program which 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 reviews the CRIS annually, in accordance with the Charging Framework. The review included consideration of the volume of applications, indirect supplier costs, and costs of monthly meetings of the Authority.

Consultation

In May 2022, the Department of Health 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 2022, 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.

The Instrument commences on 1 August 2022.

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

Details of the Instrument are set out in the Attachment.

Details of the *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2022***Section 1 Name**

Subsection 1(1) provides that the name of the Instrument is the *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2022*.

Subsection 1(2) provides that the Instrument may also be referred to as PB 65 of 2022.

Section 2 Commencement

This section provides that the whole of this instrument commences on 1 August 2022.

Section 3 Authority

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

Section 4 Schedules

This section 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 Amendments

National Health (Application Fees for Pharmacist Approvals) Determination 2020.

Item 1 Paragraph 4(a)

Item 1 amends paragraph 4(a) of the Principal Determination to substitute the application fee for an application that must be referred to the Authority in accordance with subsection 90(3A) of the Act, by removing “\$3,080” and inserting “\$1,600”.

Item 2 Paragraph 4(b)

Item 2 amends paragraph 4(b) of the Principal Determination to substitute the application fee for an application made under subsection 90(1) or 90(3) of the Act that is not required to be referred to the Authority under subsection 90(3A) of the Act, by removing “\$1,050” and inserting “\$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 2022 (PB 65 of 2022)

The *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2022* (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

Subsections 90(1) and 90(3) of the *National Health Act 1953* (Act) enable a pharmacist to make an application for approval to supply pharmaceutical benefits at particular premises. The application fees are set by the Minister under subsection 90(10) of the Act in the *National Health (Application Fees for Pharmacist Approvals) Determination 2020* (PB 31 of 2020) (the Principal Determination).

The purpose of the Instrument is to amend the Principal Determination to:

- Specify that from 1 August 2022, the fee for applications that must be referred to the Australian Community Pharmacy Authority (the Authority) is \$1,600 (reduced from \$3,080), and the fee for all other applications under subsections 90(1) and 90(3) of the Act is \$600 (reduced from \$1,050).

The changes to the fees are based on the Department of Health'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

