

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (APPLICATION FEES FOR PHARMACIST APPROVALS) AMENDMENT DETERMINATION 2021

PB 59 of 2021

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 2021* (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 a retrospective amendment to the applications fees for financial year 1 July 2020 to 30 June 2021 and prospective amendments to specify the application fees that will apply from 1 July 2021.

Retrospective amendments to the application fee for financial year 1 July 2020 to 30 June 2021

Part 1 of Schedule 1 of the Instrument amends the Principal Determination to specify that the fee for applications that must be referred to the Australian Community Pharmacy Authority (the Authority) under subsection 90(3A) of the Act is \$2,860, not \$5,530 as stated in the current Principal Determination. The amendment will have retrospective effect, commencing on 1 July 2020.

The application fee is 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 2020-21*). The review of the CRIS identified that the \$5,530 fee for applications referred to the Authority (introduced by the Principal Determination on 1 July 2020) was higher than necessary to achieve cost recovery. This was due to administrative errors in the calculation of the amount.

Applicants who have paid the higher application fee of \$5,530 will be notified and refunded the difference of \$2,670. The amendment will not have any adverse effect on applications previously submitted under subsections 90(1) or (3) of the Act in the 2020-21 financial year.

Section 12 of the *Legislation Act 2003* permits a legislative instrument to take effect retrospectively, provided that the retrospective provisions do not operate so as to adversely

affect the rights of, or impose liabilities on a person other than the Commonwealth. The retrospective provision in this Instrument is for the purpose of facilitating refunds to applicants who have been overcharged and will not disadvantage anyone other than the Commonwealth.

Application fees applying from 1 July 2021

Part 2 of Schedule 1 of the Instrument sets out amendments to the application fees in the Principal Determination to take effect from 1 July 2021. For applications that must be referred to the Authority, the fee is increased from \$2,860 to \$3,080. For all other applications, the fee is increased from \$920 to \$1,050. The increased 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 of 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

At a meeting on 23 April 2021, the Department of Health consulted with representatives from the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia about the process and timing for revision of the application fees. No concerns were raised about the proposed amendment of the application fees. Communications were also sent to peak pharmacy bodies and industry representatives in April 2021 to inform them of the review and the anticipated introduction of revised fees on 1 July 2021.

Sections 1 to 4 of the Instrument commence on the day after the Instrument is registered on the Federal Register of Legislation. The amendment to the Principal Determination in Part 1 of Schedule 1 to the Instrument commences on 1 July 2020. The amendments to the Principal Determination in Part 2 of Schedule 1 to the Instrument commence on 1 July 2021.

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 2021*

Section 1 Name of Instrument

Subsection 1(1) provides that the name of the Instrument is the *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2021*.

Subsection 1(2) provides that the Instrument may also be referred to as PB 59 of 2021.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, sections 1 to 4 of the Instrument commence on the day after the Instrument is registered on the Federal Register of Legislation; Part 1 of Schedule 1 of the Instrument commences on 1 July 2020; and Part 2 of Schedule 1 of the Instrument commences on 1 July 2021.

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

Schedule 1, Part 1 – Amendments commencing on 1 July 2020

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 “\$5,530” and inserting “\$2,860”.

Schedule 1, Part 2 – Amendments commencing 1 July 2021

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

Item 2 Paragraph 4(a)

Item 2 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 “\$2,860” and inserting “\$3,080”.

Item 3 Paragraph 4(b)

Item 3 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 “\$920” and inserting “\$1,050”.

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 2021

(PB 59 of 2021)

The *National Health (Application Fees for Pharmacist Approvals) Amendment Determination 2021* (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:

- Retrospectively reduce the fee for applications referred to the Australian Community Pharmacy Authority (the Authority) for financial year 2020-21. This would decrease the fee from \$5,530 to \$2,860, which more accurately reflects the overall costs of the approval process. The fee amount of \$5,530 was calculated incorrectly due to administrative errors. Applicants who have paid the higher amount will be refunded the difference of \$2,670.
- Specify that from 1 July 2021, the fee for applications that must be referred to the Authority is \$3,080 (increased from \$2,860), and the fee for all other applications under subsections 90(1) and 90(3) of the Act is \$1,050 (increased from \$920).

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.

Greg Hunt

Minister for Health and Aged Care