

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (APPLICATION FEES FOR PHARMACIST APPROVALS) DETERMINATION 2020

PB 31 of 2020

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.

Purpose

The purpose of this instrument (Instrument) is to determine 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.

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.

The *National Health Amendment (Pharmaceutical Benefits) Act 2019* (the Amendment Act) amended Part VII of the Act to support the efficient operation of the PBS by the introduction of an application fee for applications made under section 90 of the Act for approval to supply pharmaceutical benefits at particular premises. The introduction of an application fee is consistent with the Australian Government Charging Framework, as 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 particular pharmacy premises.

A Cost Recovery Implementation Statement (CRIS), (*Approval process for pharmacists seeking to provide Pharmaceutical Benefits Scheme medicines 2020-21*) has been prepared to provide information on how the Department of Health will implement cost recovery for this 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 Act provides for an application fee to apply to applications made under subsection 90(1) or 90(3) of the Act, and for the Minister to determine the application fees by legislative instrument.

A detailed description of this Instrument is contained in the Attachment.

Consultation

The Department of Health has consulted with the Department of Finance regarding compliance with the cost recovery framework, and with the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and the Australian Friendly Societies Pharmacies Association on the fees as set out in the Instrument.

The Instrument commences on 1 July 2020.

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

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (APPLICATION FEES FOR PHARMACIST APPROVALS) DETERMINATION 2020*

Section 1 Name of Instrument

Subsection 1(1) provides the name of the Instrument is the *National Health (Application Fees for Pharmacist Approvals) Determination 2020*.

Subsection 1(2) provides that the Instrument may also be referred to as Determination No. PB 31 of 2020.

Section 2 Commencement

This section provides that the Instrument commences on 1 July 2020.

Section 3 Authority

This section provides the Authority under which this Instrument is made, being subsection 90(10) of the *National Health Act 1953* (the Act).

Section 4 Fees for applications

Section 4 specifies the application fees that must accompany an application made under subsection 90(1) or 90(3) of the Act.

Subsection 4(a) specifies the application fee for an application that must be referred to the Australian Community Pharmacy Authority (the Authority) in accordance with subsection 90(3A) of the Act.

Subsection 4(b) specifies 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.

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) Determination 2020

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This 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 purpose of this Instrument, made under subsection 90(10) of the *National Health Act 1953* (the Act), is to determine the application fees payable for applications under section 90(1) or 90(3) of the Act, to supply pharmaceutical benefits at a particular premises.

Section 90 of the Act enables a pharmacist to make an application for approval to supply pharmaceutical benefits at a particular premises.

Human rights implications

This Instrument engages Article 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 for subsidised access to medicines for Australians. It provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. This Instrument will improve the efficiency, productivity and responsiveness of the pharmacy approval process, allowing pharmacies to provide Australian with timely access to PBS medicines. 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 does not raise any human rights issues. The Instrument advances the protection of human rights.

Greg Hunt

Minister for Health