

EXPLANATORY STATEMENT

Approved by the Minister for Health

National Health (Pharmaceutical Benefits) Amendment (Supply of Pharmaceutical Benefits Following Bankruptcy or External Administration) Regulations 2019

Variation to the National Health (Pharmaceutical Benefits) Regulations 2017

Authority

Section 140 of the *National Health Act 1953* (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 to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) provide for matters relating to the Pharmaceutical Benefits Scheme.

Subsection 2(1) of the *National Health Amendment (Pharmaceutical Benefits) Act 2019* (the Amendment Act) provides that Schedule 2 to the Amendment Act commenced by Proclamation.

Schedule 2 to the Amendment Act made amendments to the Act relating to the Pharmaceutical Benefits Scheme, providing for the continuing supply of pharmaceutical benefits in the event of the bankruptcy of the pharmacist who is approved under section 90 of the Act to supply pharmaceutical benefits at particular premises (an 'approved pharmacist'), or where there is an external administrator in relation to the pharmacy.

Subsections 4(1) to (6) of the *Acts Interpretation Act 1901*, read together, provide that regulations may be made between the passing and commencement of legislation on which they rely for their authority, as long as such regulations do not commence prior to the commencement of that legislation.

The Regulations commence on the commencement of Schedule 2 to the Amendment Act. In effect, the Regulations commence on proclamation of Schedule 2.

Purpose and operation of the Regulations

The purpose of the Regulations is to amend regulation 16 of the Principal Regulations to clarify that if the Secretary grants permission to an applicant to supply pharmaceutical benefits under the new provisions of the Act, the Secretary may allot a number to the approval, consistent with the Secretary's power to allot a number to an approval granted to a person under section 90 of the Act.

Details of the Regulations are set out in the [Attachment](#).

Consultation

The Department of Health consulted with Australian Restructuring Insolvency and Turnaround Association, the Australian Friendly Societies Pharmacy Association, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, in relation to the changes in Schedule 2 to the Amendment Act.

No consultation for the Regulations is considered necessary as the amendments deal with internal administrative processes and are considered machinery in nature.

Regulatory impact assessment

The Office of Best Practice Regulation (OBPR) assessed the changes in Schedule 2 to the Amendment Act and found those changes had no more than a minor regulatory impact, and therefore a regulatory impact statement was not required (OBPR ID 21780).

Statement of compatibility with human rights

The 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*.

The statement of compatibility set out below has been prepared to meet that requirement.

Overview of the Regulations

The *National Health (Pharmaceutical Benefits) Amendment (Supply of Pharmaceutical Benefits Following Bankruptcy or External Administration) Regulations 2019* (the Regulations) amends regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* to implement measures relating to the Pharmaceutical Benefits Scheme (PBS), to support amendments made by the *National Health Amendment (Pharmaceutical Benefits) Act 2019* (the Amending Act).

The Amendment Act enables the Secretary to grant permission to a trustee in bankruptcy to manage the supply of pharmaceutical benefits at PBS-approved pharmacy premises following bankruptcy of the approved pharmacist or where there is an external administrator in relation to the pharmacy. The Regulations provide for an administrative number to be allocated to such a permission.

Human rights implications

The Regulations are compatible with Articles 2 and 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 assists with advancement of this human right by providing subsidised access to medicines for Australians.

Schedule 2 of the Amendment Act ensures continuity of supply of PBS medicines for the community. If a pharmacy was to cease operating due to bankruptcy then the community may no longer have access to the supply of PBS medicines, which could be detrimental in communities without access to other pharmacies, such as in rural areas. The amendments will help to ensure that the community maintains reasonable access to pharmaceutical benefits.

Conclusion

The Regulations are compatible with human rights as it does not raise any human rights issues. The amendments made by the Regulations will have a beneficial impact on human rights through improved access to medicines.

Attachment

DETAILS OF THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) AMENDMENT (SUPPLY OF PHARMACEUTICAL BENEFITS FOLLOWING BANKRUPTCY OR EXTERNAL ADMINISTRATION) REGULATIONS 2019

Section 1 provides for the Regulations to be referred to as the *National Health (Pharmaceutical Benefits) Amendment (Supply of Pharmaceutical Benefits Following Bankruptcy or External Administration) Regulations 2019*.

Section 2 provides that the Regulations commence on the commencement of Schedule 2 to the *National Health Amendment (Pharmaceutical Benefits) Act 2019*. In effect, the Regulations commence on proclamation of Schedule 2.

Section 3 provides that the Authority to make the instrument is under section 140 of the *National Health Act 1953*.

Section 4 provides that Schedule 1 amends the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations).

Schedule 1 – Amendments

Item [1]

This item inserts new sub-regulation 16(3) of the Principal Regulations by providing that in circumstances where the Secretary grants permission to an applicant to supply pharmaceutical benefits under subsection 91B(1), (2) or (3) of the Act, the Secretary may allot a number to the approval that, under paragraph 91B(10)(a) of the Act, is treated as having been granted to the person under section 90 of the Act. This is consistent with the Secretary's power in sub-regulation 16(1) to allot a number to an approval granted under section 90 of the Act.