EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRESCRIBER BAG SUPPLIES) AMENDMENT DETERMINATION 2020 (No. 3)

PB 71 of 2020

Authority

Subsections 93(1) and 93AB(1) of the *National Health Act 1953* (the Act) provide for the Minister to determine the pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners, respectively, directly to patients.

Subsections 93(2) and 93AB(2) of the Act provide for the Minister to determine the maximum quantity or number of units of a pharmaceutical benefit which may be obtained during a specified period, by a medical practitioner and an authorised nurse practitioner, respectively.

The *National Health (Prescriber bag supplies) Determination 2012* (PB 73 of 2012) (the Principal Determination) determines the pharmaceutical benefits and maximum quantities of those pharmaceutical benefits for this purpose.

Purpose

The purpose of this legislative instrument, made under sections 93 and 93AB of the *National Health Act 1953* (the Act), is to amend the *National Health (Prescriber bag supplies) Determination 2012* (PB 73 of 2012) to make changes to the list of pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners, respectively, directly to patients (prescriber bag supplies) and to the maximum quantity or number of units of these pharmaceutical benefits which may be obtained during a specified period by a medical practitioner and an authorised nurse practitioner.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the addition a form of the listed drug salbutamol to the list of pharmaceutical benefits that may be supplied directly to patients as a prescriber bag supply. This change is summarised, by subject matter, in the Attachment.

Variation and revocation

Unless there is an express power to revoke or vary PB 73 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 73 of 2012.

Background

Part VII of the Act is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) of the Act provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Drugs and medicinal preparations to which Part VII applies are declared by the Minister by legislative instrument to be so under subsections 85(2) and (2AA) of the Act. These are listed drugs as defined in subsection 84(1) of the Act.

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Sections 93 and 93AB of the Act provide for certain pharmaceutical benefits to be obtained by medical practitioners and authorised nurse practitioners for direct supply for patient treatment. These pharmaceutical benefits are obtained as prescriber bag supplies and use is free of charge to the patient. Section 93AA of the Act provides for supply by authorised midwives, but that power is not exercised in the Principal Determination and has not been exercised to date. For each drug and form identified in the Schedule of the Principal Determination, the pharmaceutical benefits that may be obtained as prescriber bag supplies are all brands of pharmaceutical benefits, determined by legislative instrument under subsections 85(2), (3), and (6) of the Act, having that drug in that form.

For subsections 93(2) and 93AB(2) of the Act, the maximum quantity of each pharmaceutical benefit is the maximum quantity that a medical practitioner and an authorised nurse practitioner, respectively, may obtain during a calendar month. Where there is more than one drug and form with the same Group Number, the maximum quantity may be obtained for a pharmaceutical benefit having only one drug and form with the Group Number.

A quantity up to the maximum quantity may be obtained during a month, only if the total quantity of pharmaceutical benefits of any drug and form having the same Group Number in the possession of the prescriber bag supplier is less than the maximum quantity for the drug and form. Several Groups have two or more drugs and forms.

Consultation

This determination gives effect to recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body, established by section 100A of the Act, to make recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

Under subsection 101(4) of the Act, a drug or medicinal preparation may not be declared to be a drug or medicinal preparation to which Part VII of the Act applies unless the PBAC has recommended that it be so declared. When recommending the listing of a medicine on the PBS, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation.

This Amendment Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

This Amendment Determination commences on 1 August 2020.

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ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PRESCRIBER BAG SUPPLIES) AMENDMENT DETERMINATION 2020 (No. 3)*

Section 1 Name of Instrument

This section provides the name of this Instrument as the *National Health (Prescriber bag supplies) Amendment Determination 2020 (No. 3)* and may also be cited as PB 71 of 2020.

Section 2 Commencement

This section provides that this Instrument commences on 1 August 2020.

Section 3 Amendment of *National Health (Prescriber bag supplies) Determination 2012* (PB 73 of 2012)

This section provides that Schedule 1 amends the *National Health (Prescriber bag supplies) Determination 2012* (PB 73 of 2012).

Schedule Amendments

The amendment in Schedule 1 involves the addition of a form of a listed drug to the list of Pharmaceutical Benefits that may be supplied directly to patients as a prescriber bag supply. This change is summarised below.

SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (PRESCRIBER BAG SUPPLIES) DETERMINATION 2012* MADE BY THIS INSTRUMENT

Form Added

Listed Drug	***Form***
Salbutamol	Pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation)

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Statement of Compatibility with Human Rights

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

National Health (Prescriber bag supplies) Amendment Determination 2020 (No. 3)

(PB 71 of 2020)

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 Legislative Instrument

The *National Health (Prescriber bag supplies) Amendment Determination 2020 (No. 3)* amends the *National Health (Prescriber bag supplies) Determination 2012*, made under sections 93 and 93AB of the *National Health Act 1953* (the Act), which provides for certain pharmaceutical benefits to be obtained, and supplied, by medical practitioners and authorised nurse practitioners directly to patients for treatment (prescriber bag supplies) and specifies the maximum amount of these pharmaceutical benefits that may be obtained by medical practitioners and authorised nurse practitioners in any calendar month. These pharmaceutical benefits are obtained for use for patient treatment as prescriber bag supplies and are free of charge to patients.

The amendment in Schedule 1 involves the addition of a form of a listed drug to the list of Pharmaceutical Benefits that may be supplied directly to patients as a prescriber bag supply.

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 for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

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

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