EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRESCRIBER BAG SUPPLIES) AMENDMENT (APRIL UPDATE) DETERMINATION 2025

PB 27 of 2025

Authority

Subsections 93(1), 93AA(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, authorised midwives and authorised nurse practitioners, respectively, directly to patients under the Pharmaceutical Benefits Scheme (PBS).

Subsections 93(2), 93AA(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, an authorised midwife and an authorised nurse practitioner, respectively.

The *National Health (Prescriber Bag Supplies) Determination 2024* (PB 29 of 2024) (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, 93AA and 93AB of the *National Health Act 1953* (the Act), is to amend the *National Health (Prescriber Bag Supplies) Determination 2024* (PB 29 of 2024) to make changes to the list of pharmaceutical benefits that may be supplied by medical practitioners, authorised midwives 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, an authorised midwife and an authorised nurse practitioner.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the deletion of a form of the listed drug salbutamol from 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 29 of 2024 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 29 of 2024.

Background

Part VII of the Act is the legislative basis of the 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.

Sections 93, 93AA and 93AB of the Act provide for certain pharmaceutical benefits to be obtained by medical practitioners, authorised midwives and authorised nurse practitioners, respectively, for direct supply for patient treatment. These pharmaceutical benefits are obtained as prescriber bag supplies and use is free of charge to the patient. 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), 93AA(2) and 93AB(2) of the Act, the maximum quantity of each pharmaceutical benefit is the maximum quantity that a medical practitioner, an authorised midwife, 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 among the ranks of 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. Additional members may be 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 Schedule of Pharmaceutical Benefits, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, and the medicine's 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 April 2025.

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PRESCRIBER BAG SUPPLIES) AMENDMENT (APRIL UPDATE) DETERMINATION 2025*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Prescriber Bag Supplies) Amendment (April Update) Determination 2025* and may also be cited as PB 27 of 2025.

Section 2 Commencement

This section provides that this Instrument commences on 1 April 2025.

Section 3 Authority

This section specifies that sections 93, 93AA and 93AB of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendment in Schedule 1 involves the deletion of a form of a listed drug for 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 2024* MADE BY THIS INSTRUMENT

Form Deleted

Listed Drug	*Form*
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A)

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 (April Update) Determination 2025

(PB 27 of 2025)

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 *National Health (Prescriber Bag Supplies) Amendment (April Update) Determination 2025* amends the *National Health (Prescriber Bag Supplies) Determination 2024*, (the Principal Instrument) made under subsections 93, 93AA and 93AB of the *National Health Act 1953* (the Act), which provides for certain pharmaceutical benefits to be obtained, and supplied, by medical practitioners, authorised midwives 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, authorised midwives 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.

Human Rights Implications

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights (the Committee) reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

This Instrument advances the right to health and the right to social security by ensuring that amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (the Listing Instrument) that affect the pharmaceutical benefits which can be supplied directly to the patient for emergency use (prescriber bag supplies) are made concurrently. This Instrument provides for the deletion of a form of the listed drug salbutamol from the list of pharmaceutical benefits that may be supplied directly to patients as a prescriber bag supply.

The Listing Instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The 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.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from PBAC is tabled with the monthly amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024). An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of the form of a drug in the abovementioned instruments, would not result in an unmet clinical need except where indicated for a particular drug or form of drug below. The delisting of this item will not affect access to the drugs, as affected patients will be able to access alternative medicines through the PBS and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these fees are up to $31.60 for general patients and up to $7.70 for concession card holders.

The drug salbutamol in the form nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of salbutamol in the form nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 30 November 2024. Patient access has not been affected as the approved form of the drug is now available and remains PBS subsidised and accessible for patients.

Conclusion

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

Rebecca Richardson
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care