

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

PB 38 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 is to amend the *National Health (Prescriber Bag Supplies) Determination 2024* (PB 29 of 2024) to enable authorised midwives to supply certain pharmaceutical benefits directly to patients (prescriber bag supplies).

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), which commenced 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 – Retrospective amendments

Schedule 1 of this Instrument makes retrospective amendments to the Principal Determination in line with recommendations from the PBAC. Schedule 1 of the Principal Determination was amended on 1 February 2025 to enable certain pharmaceutical benefits to be supplied by authorised midwives under prescriber bag arrangements. This Instrument makes further amendments to the Principal Determination to enable authorised midwives, for the purposes of section 93AA of the Act, to obtain and supply prescriber bag supplies.

Although this Instrument commences retrospectively, the changes are not contrary to subsection 12(2) of the *Legislation Act 2003* as they would not apply to a person (other than the Commonwealth) to the extent they would retrospectively diminish that person's rights, or retrospectively impose new liabilities on them in respect of things done or omitted to be done at the time this Instrument is registered. Rather, the changes are beneficial in nature as they ensure authorised midwives can participate in the prescriber bag arrangements provided for in the Act in relation to certain pharmaceutical benefits specified in Schedule 1 to the Principal Determination.

Variation

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that 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.

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to amend 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. This Instrument exercises the powers provided under section 93AA of the Act for the first time. 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 Instrument 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 February 2025.

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

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Prescriber Bag Supplies) Amendment (Practitioner Update) Determination 2025* and may also be cited as PB 38 of 2025.

Section 2 Commencement

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

Section 3 Authority

This section specifies that sections 93, 93AA and 93AB of the *National Health Act 1953* (the Act) 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. The Schedule amends the *National Health (Prescriber Bag Supplies) Determination 2024 (PB 29 of 2024)* (the Principal Determination).

Schedule 1 Amendments

Item 1 – Section 3

Item 1 inserts a reference to section 93AA of the Act in section 3 of the Principal Determination. This clarifies that the Principal Determination is made under sections 93, 93AA and 93AB of the Act.

Item 2 – Section 4

Item 2 inserts a definition for *authorised midwife* in section 4 of the Principal Determination. The term *authorised midwife* is defined to have the same meaning as in Part VII of the Act. Section 84 of the Act defines *authorised midwife* to mean an eligible midwife in relation to whom an approval is in force under section 84AAF.

Item 3 – At the end of section 6

Item 3 inserts new subsection 6(3) to the Principal Determination. Section 6 is amended to allow authorised midwives to supply certain pharmaceutical benefits under prescriber bag arrangements. New subsection 6(3) provides that an authorised midwife is authorised to supply each pharmaceutical benefit that has the drug in the relevant form if the initials “MW” are mentioned in the column in Schedule 1 of the Principal Determination headed “Prescriber Bag Supplier”.

Item 4 – Subsection 7(1)

Item 4 repeals and substitutes subsection 7(1) of the Principal Determination to include references to the term *authorised midwife* and to subsection 93AA(2) of the Act. New subsection 7(1) provides that section 7 determines the maximum number of units of a pharmaceutical benefit that has a drug in a relevant form which may be obtained by a medical practitioner, an authorised midwife or an authorised nurse practitioner (a *practitioner*) in a calendar month.

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 (Practitioner Update) Determination 2025 **(PB 38 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 (Practitioner Update) Determination 2025* amends the *National Health (Prescriber Bag Supplies) Determination 2024*, (the Principal Instrument) made under sections 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 enables authorised midwives to supply prescriber bag supplies directly to patients.

Although the Instrument commences retrospectively, the changes are not contrary to subsection 12(2) of the *Legislation Act 2003* as they would not apply to a person (other than the Commonwealth) to the extent they would retrospectively diminish that person's rights or retrospectively impose new liabilities on them in respect of things done or omitted to be done at the time this Instrument is registered. Rather, the changes are beneficial in nature as they ensure authorised midwives can participate in the prescriber bag arrangements provided for in the Act in relation to certain pharmaceutical benefits specified in Schedule 1 to the Principal Instrument.

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.

Written advice from PBAC is tabled with the monthly amendments to the Listing Instrument. 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.

Conclusion

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

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