

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Prescriber Bag Supplies) Determination 2024

PB 29 of 2024

Purpose and operation

The *National Health (Prescriber Bag Supplies) Determination 2024* (2024 Prescriber Bag Determination) contains the list of pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners, respectively, directly to patients (prescriber bag supplies) and 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 prescriber bag provisions (Sections 93, 93AA and 93AB) of the *National Health Act 1953* (the Act) enable authorised prescribers to obtain certain PBS medicines to supply free to patients for emergency use. The 2024 Prescriber Bag Determination determines the pharmaceutical benefits and maximum quantities of those pharmaceutical benefits for this purpose.

The 2024 Prescriber Bag Determination replaces the *National Health (Prescriber bag supplies) Determination 2012*, which sunsets on 1 April 2024.

Background

The PBS is a central feature of Medicare, Australia's universal health care system which helps Australians with the cost of their health care. 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. The 2024 Prescriber Bag Determination is a component of the PBS.

From 1 April 2024, the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) sets out the pharmaceutical benefits that may be supplied to patients at Government-subsidised prices under the PBS. The drugs or medicinal preparations and, where relevant, forms, manners of administration and brands making up pharmaceutical benefits are declared or determined under subsections 85(2), (3), (5) and (6) of the Act, respectively.

Authority

Sections 93 and 93AB of the Act provide that the Minister may determine the pharmaceutical benefits that medical practitioners and authorised nurse practitioners respectively may supply, without prescription, under prescriber bag arrangements and the maximum quantity of those pharmaceutical benefits that they may obtain during a specified period for the purposes of prescriber bag supply.

Consultation

The Department has consulted extensively internally and with Services Australia and the Department of Veterans' Affairs during the remake process. Further comments were sought in

relation to prescriber bag supplies from the Pharmacy Guild of Australia, Pharmaceutical Society of Australia and the Medical Software Industry Association regarding the 2024 Prescriber Bag Determination to ensure any issues were recognised and addressed. No significant issues were raised during consultations.

The 2024 Prescriber Bag Determination also 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.

General

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

This instrument commences on 1 April 2024.

Details of the instrument are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the National Health (Prescriber Bag Supplies) Determination 2024

Part 1 – Preliminary

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Prescriber Bag Supplies) Determination 2024* (2024 Prescriber Bag Determination) and may also be cited as PB 29 of 2024.

Section 2 – Commencement

Section 2 provides that the 2024 Prescriber Bag Determination commences on 1 April 2024.

Section 3 – Authority

Section 3 provides that the 2024 Prescriber Bag Determination is made under sections 93 and 93AB of the *National Health Act 1953* (Act).

Section 4 – Definitions

Section 4 sets out the definitions for the 2024 Prescriber Bag Determination.

The term “Act” is defined to mean the *National Health Act 1953*.

The terms “authorised nurse practitioner”, “pharmaceutical benefit” and “pharmaceutical benefit has a drug” are defined to have the same meaning as in Part VII of the Act.

For the meaning of the term “pharmaceutical benefit that has a drug in a relevant form”, readers are pointed to section 5 of the 2024 Prescriber Bag Determination.

A note in section 4 provides that under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act. This includes the term “medical practitioner”.

Section 5 – References to a pharmaceutical benefit that has a drug in a relevant form

Section 5 provides that a reference in the 2024 Prescriber Bag Determination to a “pharmaceutical benefit that has a drug in a relevant form” is a reference to a pharmaceutical benefit that has a drug mentioned in an item in Schedule 1 in the column headed “Listed Drug” in the form mentioned for that drug in the column in Schedule 1 headed “Form”.

For example, Schedule 1 mentions the drug adrenaline (epinephrine) in the form injection 1 mg (as acid tartrate) in 1 mL (1 in 1,000). References to a pharmaceutical benefit that has a drug in a relevant form in the instrument will therefore capture each pharmaceutical benefit that has the drug adrenaline (epinephrine) in the form injection 1 mg (as acid tartrate) in 1 mL (1 in 1,000), irrespective of the brand or manner of administration of the pharmaceutical benefit.

Part 2 – Authorisation of practitioners and maximum quantity (number of units)

Section 6 – Authorisation of practitioners to supply pharmaceutical benefits

Section 6 is made for the purposes of subsection 93(1) and subsection 93AB(1) of the Act. It authorises medical practitioners and authorised nurse practitioners to supply certain pharmaceutical benefits under prescriber bag arrangements.

Section 6 provides that where an item in Schedule 1 mentions a drug in a form:

- a medical practitioner is authorised to supply each pharmaceutical benefit that has the drug in the relevant form if the initials “MP” are mentioned in the column headed “Prescriber Bag Supplier” for the item; and
- an authorised nurse practitioner is authorised to supply each pharmaceutical benefit that has the drug in the relevant form if the initials “NP” are mentioned in that column for the item.

The 2024 Prescriber Bag Determination does not make any change to the pharmaceutical benefits that may be supplied under prescriber bag arrangements by medical practitioners and authorised nurse practitioners that applied under the *National Health (Prescriber bag supply) Determination 2012* (2012 Prescriber Bag Determination).

Section 7 – Maximum quantity (number of units)

Section 7 is made for the purposes of subsection 93(2) and subsection 93AB(2) of the Act.

Subsection 7(1) provides that the section 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 or an authorised nurse practitioner (a practitioner) in a calendar month. The *National Health (Pharmaceutical Benefits) Regulations 2017* deal with the process by which practitioners can obtain pharmaceutical benefits for prescriber bag supply.

Subsection 7(2) provides that the maximum number of units is the number mentioned in the column in Schedule 1 headed “Maximum Quantity” for that drug in that form.

For example, for the drug chlorpromazine in the form injection containing chlorpromazine hydrochloride 50 mg in 2 mL, the maximum number of units of any pharmaceutical benefit that has the drug in the form that can be obtained by a practitioner in a calendar month is 10.

Subsection 7(3) sets out modifications to the maximum number of units that can be obtained in a calendar month where pharmaceutical benefits having the drug and form are in a ‘group’ that also contains pharmaceutical benefits with other drugs and forms. It provides that if a practitioner has already obtained 1 or more units of a pharmaceutical benefit that has a drug in a relevant form in a group in the same calendar month, the maximum number of units of any other pharmaceutical benefit that has a drug in a relevant form in that group is zero for that calendar month.

Subsection 7(4) provides that a group is each pharmaceutical benefit that has a drug in a relevant form which has the same number mentioned for the drug and form in the column in Schedule 1 headed “Group Number”.

For example, pharmaceutical benefits that have the drug chlorpromazine in the form injection containing chlorpromazine hydrochloride 50 mg in 2 mL are in the same group as pharmaceutical benefits that have the drug haloperidol in the form injection 5 mg in 1 mL. If a practitioner has already obtained any amount of any pharmaceutical benefit with chlorpromazine in the form injection containing chlorpromazine hydrochloride 50 mg in 2 mL, they cannot obtain any units of any pharmaceutical benefit that has haloperidol in the form injection 5 mg in 1 mL during the same calendar month.

Section 7 of the 2024 Prescriber Bag Determination corresponds to subsections 6(1), 6(2) and 6(4) of the 2012 Prescriber Bag Determination. Subsection 6(3) of the 2012 Prescriber Bag Determination is now subsection 33(3A) of the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Schedule 1 - Pharmaceutical benefits that may be supplied by authorised suppliers

The Schedule sets out the drugs and forms that can be supplied by each type of prescriber bag supplier (i.e. medical practitioners and authorised nurse practitioners) together with the applicable maximum quantities. It also identifies the groups for the drugs and forms.

The 2024 Prescriber Bag Determination does not change the pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners under prescriber bag arrangements from those available under the 2012 Prescriber Bag Determination.

Statement of Compatibility with Human Rights

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

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This Disallowable Legislative 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 Disallowable Legislative Instrument

The *National Health (Prescriber Bag Supplies) Determination 2024* (the 2024 Prescriber Bag Determination) is a remake of the *National Health (Prescriber bag supplies) Determination 2012* (the 2012 Prescriber Bag Determination), 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 2024 Prescriber Bag Determination does not change the pharmaceutical benefits that may be supplied by medical practitioners and authorised nurse practitioners under prescriber bag arrangements from those available under the 2012 Prescriber Bag Determination.

Human rights implications

This Disallowable Legislative 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. The 2024 Prescriber Bag Determination ensures continuity of the operations currently mandated in the 2012 Prescriber Bag Determination to enable prescribers to obtain certain PBS medicines to supply free to patients for emergency use.

Conclusion

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

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