

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLAGIC PROGRAM) SPECIAL ARRANGEMENT 2021

(PB 31 of 2021)

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Purpose

The purpose of the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* (the Special Arrangement) is to provide for the continued operation of the Paraplegic and Quadriplegic (ParaQuad) Program which assists people with paraplegia and quadriplegia to access bowel management medicines free of charge.

The program has been in operation for approximately 40 years. An internal review of the ParaQuad Program was undertaken in 2013-14 as part of the general review of section 100 programs. No changes were made to the program as a result of the review.

To be eligible to participate in the ParaQuad program, a person must have a paraplegia or quadriplegia and be a member of a participating paraplegic and quadriplegic association, currently there are two:

- The Paraplegic & Quadriplegic Association of NSW (ABN 42 000 355 948); and
- Independence Australia Group (ABN 80 973 805 243).

All pharmaceutical benefits available under this Special Arrangement are also available through the Pharmaceutical Benefits Scheme (PBS) with a PBS prescription.

The *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010* is due to sunset on 1 April 2021. The purpose of the Special Arrangement is to repeal and replace the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010*, as well as introduce the following amendments:

- Removing the definition of ‘other Special Arrangement’ as no longer used in the Special Arrangement;
- Removing two associations and adding one association to the list of paraplegic and quadriplegic associations authorised to supply pharmaceutical benefits under the Special Arrangement; and
- Provide for internal merits review of decisions made by the Chief Executive Medicare.

A provision by provision description of the Special Arrangement is contained in the Attachment.

Consultation

Since early 2020 the Department of Health (the Department) have been meeting monthly with the two authorised associations who currently deliver the ParaQuad program, the Paraplegic & Quadriplegic Association of NSW and Independence Australia Group, to discuss the imminent sunset of the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010*.

During the consultation process both associations have been supportive of continuing the existing arrangements. The Department continues to meet regularly with the authorised associations with regard to policy changes for the program.

The Department also consulted with Services Australia our claims partner for the ParaQuad program. On 4 March 2021, Services Australia confirmed they had no concerns with continuing the current arrangements as outlined in the Special Arrangement.

Pharmaceutical Benefits Advisory Committee (PBAC)

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

PBAC is an independent expert body established by section 100A of the Act which makes 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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the PBS, 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.

Pharmaceutical companies are consulted throughout the process of changes to the listings on the PBS. This includes consultation through the PBAC process.

The Special Arrangement commences on the day after it is registered. The Special Arrangement is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021*

Section 1 Name

This section provides that the Special Arrangement is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* (the Special Arrangement) and may also be cited as PB 31 of 2021.

Section 2 Commencement

This section provides that the Special Arrangement commences on the day after it is registered.

Section 3 Authority

Section 3 provides that the Special Arrangement is made under section 100 of the *National Health Act 1953*.

Section 4 Definitions

A number of expressions used in the Special Arrangement are defined in section 4. The definition of ‘other Special Arrangement’ has been removed as it is no longer used in the Special Arrangement.

Section 5 Pharmaceutical benefits covered by this Special Arrangement

This section provides for the pharmaceutical benefits that are covered by the Special Arrangement. They are the pharmaceutical benefits (i.e., the brands of the listed drugs in the forms and with the manners of administration) set out in Schedule 1 to the Special Arrangement.

Section 6 Application of Part VII of the Act

Subsection 100(3) of the Act provides that Part VII of the Act, and regulations or other instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Subsection 6(1) provides that the pharmaceutical benefits supplied under the Special Arrangement are supplied under Part VII. This is the situation under the Act and the subsection confirms that this is not intended to be modified by the Special Arrangement. Subsection 6(2) confirms that the provisions of Part VII, and regulations and other instruments made for Part VII apply subject to the Special Arrangement.

Section 7 Responsible person

This section provides for the responsible persons for the brands of pharmaceutical items covered by the Special Arrangement. The responsible persons have been determined by the Minister to be the responsible persons under section 84AF of the Act in another legislative instrument and are included in the Special Arrangement for transparency.

Section 8 No prescriber or prescription

Section 12 of the Special Arrangement provides that an authorised association may supply a pharmaceutical benefit to an eligible person on the person’s request, and, without a prescription for the supply to the person. This section therefore provides that the PBS prescriber and PBS prescription

requirements which would apply for general supply under Part VII of the Act do not apply for supply under the Special Arrangement.

That is, there is no requirement for a PBS prescriber or a PBS prescription, and therefore there are no prescription circumstances to be met by a PBS prescriber, and no maximum quantities or numbers of units that may, in 1 prescription, be directed to be supplied on any 1 occasion. There are also no requirements regarding repeat prescriptions.

Section 9 Paraplegic and quadriplegic associations

This section provides that the following paraplegic and quadriplegic associations are authorised to supply pharmaceutical benefits under this Special Arrangement:

- The Paraplegic & Quadriplegic Association of NSW (ABN 42 000 355 948);
- Independence Australia Group (ABN 80 973 805 243).

Paraquad Victoria were previously listed as an authorised association, but this has been updated due to their name change to Independence Australia Group. Spinal Injuries Association Inc are no longer an authorised association under this Special Arrangement as they no longer supply pharmaceutical benefits.

Section 10 Eligible persons

This section provides that a person is eligible to receive pharmaceutical benefits from an authorised association if the person:

- is an eligible person within the meaning of the *Health Insurance Act 1973*;
- has paraplegia or quadriplegia; and
- is a member of the authorised association.

The *Health Insurance Act 1973* defines an eligible person to be an Australian resident or eligible overseas representative, which are further defined in that Act. It also provides that certain visitors to Australia will be treated as eligible persons.

Section 11 Maximum amount

This section provides that the maximum amount of the pharmaceutical item in a pharmaceutical benefit that may, during a month, be supplied by an authorised association to an eligible person is the amount mentioned in the column in Schedule 1 headed 'Maximum Amount' for the pharmaceutical benefit.

Section 12 Supply

Subsection 12(1) provides that an authorised association may supply a pharmaceutical benefit to an eligible person on the person's request, and, despite section 89 of the Act, without a prescription for the supply to the person.

A note to subsection 12(1) states that section 89 provides for pharmaceutical benefits to be supplied only on prescription.

Subsection 12(2) provides that the authorised association may supply the pharmaceutical benefit to the person by making the pharmaceutical benefit available to be picked up by the person at the authorised association's premises, or, sending the pharmaceutical benefit to the person.

Section 13 Co-payment etc. not to be made

Section 13 provides that an authorised association must not demand or receive a payment or other valuable consideration for the supply of a pharmaceutical benefit under this Special Arrangement, other than a payment from the Commonwealth under section 14, or a charge mentioned in section 15.

Section 14 Payment from Commonwealth

Subsection 14(1) provides that an authorised association that supplies a pharmaceutical benefit is entitled to be paid by the Commonwealth for the supply the amount worked out under subsection 14(2).

Paragraph 14(2)(a) provides for payments to be based on the price to pharmacists worked out under the paragraph 98B(1)(a) determination; the price to pharmacists is the approved ex-manufacturer price or the proportional ex-manufacturer price, plus a wholesale mark-up.

However, where there is a claimed price for the pack quantity, paragraph 14(2)(b) applies and payments are based on the claimed price (which is an ex-manufacturer price) plus a wholesale mark-up worked out under subsection (3).

There is also a 2.75% handling fee.

Section 15 Charge for delivery

This section provides that if an authorised association supplies a pharmaceutical benefit by sending it to a person the association may charge the person an amount that is equal to the cost of sending the pharmaceutical benefit to the person.

Section 16 Claims for payment

Subsection 16(1) provides that an authorised association that wants to receive payment for the supply of a pharmaceutical benefit under this Special Arrangement must make a claim for payment to the Chief Executive Medicare.

Subsection 16(2) provides that the Chief Executive Medicare is to determine the amount payable for a claim made under subsection 16(1) and to make any payment relating to the claim.

Subsection 16(3) provides that, despite section 99AAA of the Act, the authorised association must submit its claims for the supplies it makes during a month on a form that is approved in writing by the Chief Executive Medicare for this section. Authorised associations can obtain the form from Services Australia.

A note to section 16 provides that section 99AAA of the Act provides for rules to be made by the Minister about procedures for claims for payment.

Section 17 Stock of pharmaceutical benefits etc.

This section provides that an authorised association may order a pharmaceutical benefit from the responsible person or wholesaler of the pharmaceutical benefit, and, may keep in stock at its premises an adequate supply of pharmaceutical benefits for supply under the Special Arrangement.

Section 18 Internal review of decisions

Subsection 18(1) provides that a person (in practical terms, an authorised association) who is affected by a decision of the Chief Executive Medicare under this Special Arrangement may apply for review of the decision by the Secretary. An application must be in writing and made within 28 days after the

day the decision first came to the notice of the applicant, or a longer period if the Secretary allows (subsection 18(2)).

On receiving an application for review of a decision, the Secretary must review the decision and affirm, vary or set aside the decision. If the decision is **affirmed**, the decision remains unchanged; if the decision is **varied**, the decision is changed or altered in some way; and if the decision is **set aside**, a new decision is made in substitution (subsection 18(3)).

Subsection 18(4) provides that a decision by the Secretary on review takes effect on the day specified in the decision on review, or, where a day is not specified, or the day the decision on review was made. After making a decision, the Secretary must give the applicant written notice of the terms of the decision and the reasons for decision (subsection 18(5)).

In practice, it is intended that the Secretary will delegate the power to review decisions to SES employees in the Department of Health. As a matter of administrative practice, the review of the decision will not be undertaken by the decision-maker, but by a different person.

The provision for internal merits review and supporting administrative practice will ensure that authorised associations have access to a mechanism for the reconsideration of decisions by the Department, which ensures procedural fairness and accountability.

External merits review of decisions made under the Special Arrangement is not available under the Act. Section 105AB of the Act, which is in Part VIIA, sets out the decisions of the Secretary that can be the subject of review by the Administrative Appeals Tribunal. The decisions that are listed do not include decisions made by the Secretary under instruments made under s 100 of the Act, and s 100(3) does not provide for the modification of provisions of Part VIIA.

Further, decisions under section 16 are not easily susceptible to merits review. In relation to a decision to make a payment under section 16, it is arguable that the Special Arrangement creates an obligation on the part of the Chief Executive Medicare or delegate to act in a certain way upon the occurrence of a specified set of circumstances.

Subsection 16(1) provides that an authorised association that wants to receive payment for the supply of a pharmaceutical benefit under this Special Arrangement must make a claim for payment to the Chief Executive Medicare, with the requirements for making that claim set out in subsection 16(3). Given the nature of the requirements, the question of whether those requirements are met will be a question of fact – either the requirements are met, or they are not. The requirements do not require the Chief Executive Medicare or delegate to make an evaluative judgment. Further, the Chief Executive Medicare or delegate has no discretion to decide that a requirement that has not been met should be taken to have been met.

Where the requirements are met, subsection 16(2) requires the Chief Executive Medicare to determine the amount payable for the claim, and to make the relevant payment to the authorised association,

A decision under section 18 will be subject to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*, and under s 75(v) of the Constitution or section 39B of the *Judiciary Act 1903*, as a decision of an officer of the Commonwealth.

Section 19 Application of this Special Arrangement

Section 19 provides that this Special Arrangement applies to the supply of a pharmaceutical benefit from the day after the Special Arrangement is registered. The repealed Special Arrangement applies earlier.

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

This Schedule sets out the pharmaceutical benefits covered by the Special Arrangement and a number of related matters. Some of the matters have been declared or determined in other legislative instruments and are included in the Special Arrangement for reasons of transparency. The pharmaceutical benefits covered by the Special Arrangement have been determined in the Special Arrangement (section 5) even though the declarations and determinations which provide for those medicines to be pharmaceutical benefits have been made in another instrument.

The matters dealt with in the various columns of the Schedule, the corresponding provisions of the Act and the related sections of the Special Arrangement are set out in the table below.

<u>Column in Schedule 1</u>	<u>Provision of the Act</u>	<u>Section of the Instrument</u>
Listed Drug	Subsection 85(2)	Section 5
Form	Subsection 85(3)	Section 5
Manner of Administration	Subsection 85(5)	Section 5
Brand	Subsection 85(6)	Section 5
Responsible Person	Subsection 84AF(1)	Section 7
Maximum Amount	Subsection 100(1)	Section 11

Schedule 2 Responsible person codes

This Schedule relates to section 7 of the Special Arrangement. The responsible person for each brand of a pharmaceutical item is identified in the column headed 'Responsible Person' in Schedule 1 by a two letter code. Schedule 2 sets out the name of the responsible person and their ABN, if any, for each code.

Statement of Compatibility with Human Rights

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

National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021

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This Special Arrangement 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 Special Arrangement

The purpose of the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* (the Special Arrangement) is to provide for the continued operation of the Paraplegic and Quadriplegic (ParaQuad) Program which assists people with paraplegia and quadriplegia to access bowel management medicines free of charge. To be eligible to participate in the ParaQuad program, a person must have a paraplegia or quadriplegia and be a member of a participating paraplegic and quadriplegic association, currently there are two:

- The Paraplegic & Quadriplegic Association of NSW (ABN 42 000 355 948); and
- Independence Australia Group (ABN 80 973 805 243).

All pharmaceutical benefits available under this Special Arrangement are also available through the Pharmaceutical Benefits Scheme (PBS) with a PBS prescription.

Additionally, the Special Arrangement, made under section 100 of the *National Health Act 1953* (the Act), will repeal and replace the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010* as well as introduce the following amendments:

- removing the definition of ‘other Special Arrangement’ as no longer used in the Special Arrangement;
- remove two associations and add one association to the list of paraplegic and quadriplegic associations authorised to supply pharmaceutical benefits under the Special Arrangement; and
- provide for internal merits review of decisions made by the Chief Executive Medicare.

Schedule 1 to this Special Arrangement provides for additions, deletions and changes to drugs, forms, manners of administration, brands, responsible person codes and maximum amounts for pharmaceutical benefits listed in Schedule 1 of the Special Arrangement. It also provides for additions, deletions and changes to responsible person codes, responsible persons and their Australian Business Numbers listed in Schedule 2 of the Special Arrangement.

Human rights implications

This Special Arrangement engages the right to equality and non-discrimination contained Article 2(2) of the International Covenant on Economic, Social and Cultural Rights and the right to health contained in Article 12 of that covenant, 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 the 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 Special Arrangement is compatible with human rights because it promotes the protection of human rights.

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