National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021

PB 31 of 2021

made under section 100 of the

National Health Act 1953

Compilation No. 1

Compilation date:	1 July 2021
Includes amendments up to:	F2021L00916
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Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* that shows the text of the law as amended and in force on 1 July 2021 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name

(1) This Special Arrangement is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021*.

(2) This Special Arrangement may also be cited as PB 31 of 2021.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	The day after this instrument is registered.	16 March 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This Special Arrangement is made under section 100 of the *National Health Act 1953*.

4 Definitions

In this Special Arrangement:

ABN has the same meaning as in the *A New Tax System (Australian Business Number) Act 1999*.

Act means the *National Health Act 1953*.

authorised association means a paraplegic and quadriplegic association authorised to supply pharmaceutical benefits under this Special Arrangement by section 9.

eligible person means a person that is eligible to receive pharmaceutical benefits under section 10.

Note: Terms used in this Special Arrangement have the same meaning as in the Act—see section 13 of the *Legislation Act 2003*. These terms include:

- approved ex-manufacturer price
- brand
- claimed price
- listed drug
- pack quantity
- pharmaceutical benefit
- pharmaceutical item
- proportional ex-manufacturer price
- responsible person.

5 Pharmaceutical benefits covered by this Special Arrangement

(1) This Special Arrangement applies to each pharmaceutical benefit mentioned in Schedule 1.

(2) Each pharmaceutical benefit to which this Special Arrangement applies is a brand of a listed drug mentioned in Schedule 1:

(a) in the form mentioned in Schedule 1 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note: Each listed drug mentioned in Schedule 1 has been declared by the Minister under subsection 85(2) of the Act. The form, manner of administration and brand mentioned in Schedule 1 have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

6 Application of Part VII of the Act

(1) Each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.

(2) A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies subject to this Special Arrangement.

Note: See subsection 100(3) of the Act.

7 Responsible person

(1) If a code is mentioned in the column in Schedule 1 headed ‘Responsible Person’ for a brand of a pharmaceutical item, the person mentioned in paragraph (2)(a) is the responsible person for the brand of the pharmaceutical item.

(2) For subsection (1):

(a) the person is the person mentioned in Schedule 2 for the code, with the ABN, if any, mentioned in Schedule 2 for the person; and

(b) the pharmaceutical item is the listed drug mentioned in Schedule 1:

(i) in the form mentioned in Schedule 1 for the listed drug; and

(ii) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note: A person identified by a code in the column headed 'Responsible Person' in Schedule 1 has been determined by the Minister, under section 84AF of the Act, to be the responsible person for the brand of the pharmaceutical item.

8 No prescriber or prescription

(1) If a pharmaceutical benefit is supplied in accordance with this Special Arrangement, the following determinations do not apply to the supply:

(a) a determination made under section 88 of the Act about PBS prescribers for the pharmaceutical benefit;

(b) a determination made under paragraph 85(7)(b) of the Act about the circumstances in which a prescription for the pharmaceutical benefit may be written;

(c) a determination made under paragraph 85A(2)(a) of the Act about the maximum quantities or number of units of the pharmaceutical item in the pharmaceutical benefit that may, in 1 prescription, be directed to be supplied on any 1 occasion;

(d) a determination made under paragraph 85A(2)(b) of the Act about the maximum number of occasions on which the pharmaceutical benefit may be directed to be supplied in a prescription.

Part 2—Supply for the paraplegic and quadriplegic program

9 Paraplegic and quadriplegic associations

The following paraplegic and quadriplegic associations are authorised to supply pharmaceutical benefits under this Special Arrangement:

(a) The Paraplegic & Quadriplegic Association of NSW (ABN 42 000 355 948); and

(b) Independence Australia Group (ABN 80 973 805 243).

10 Eligible persons

A person is eligible to receive a pharmaceutical benefit from an authorised association if the person:

(a) is an eligible person within the meaning of the *Health Insurance Act 1973*; and

(b) has paraplegia or quadriplegia; and

(c) is a member of the association.

11 Maximum amount

(1) 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.

(2) For subsection (1):

(a) the pharmaceutical item is the listed drug mentioned in Schedule 1:

(i) in the form mentioned in Schedule 1 for the listed drug; and

(ii) with the manner of administration mentioned in Schedule 1 for the form of the listed drug; and

(b) the pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:

(i) in the form mentioned in Schedule 1 for the listed drug; and

(ii) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

12 Supply

(1) An authorised association may supply a pharmaceutical benefit to an eligible person:

(a) on the person's request; and

(b) despite section 89 of the Act, without a prescription written for the supply to the person.

Note: Section 89 of the Act provides for pharmaceutical benefits to be supplied only on prescription.

(2) The association may supply the pharmaceutical benefit to the person by:
  (a) making the pharmaceutical benefit available to be picked up by the person at the association's premises; or
  (b) sending the pharmaceutical benefit to the person.

13 Co-payment etc. not to be made

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) a payment from the Commonwealth under section 14.
  (b) a charge mentioned in section 15.

14 Payment from Commonwealth

(1) An authorised association that supplies a pack quantity of a pharmaceutical benefit is entitled to be paid by the Commonwealth for the supply the amount worked out under subsection (2).

(2) For subsection (1), the amount is:
  (a) if there is no claimed price for the pack quantity of the pharmaceutical benefit:
    (i) the price to pharmacists for the pack quantity worked out under the determination under paragraph 98B(1)(a) of the Act; and
    (ii) a handling fee of 2.75% of that amount; or
  (b) if there is a claimed price for the pack quantity of the pharmaceutical benefit:
    (i) the claimed price for the pack quantity plus a wholesale mark-up calculated in accordance with subsection (3); and
    (ii) a handling fee of 2.75% of that amount.

(3) For paragraph (2)(b), the wholesale mark-up for the pack quantity of the pharmaceutical benefit is to be worked out using the methodology for calculating the wholesale mark-up for ready-prepared pharmaceutical benefits in the determination under paragraph 98B(1)(a) of the Act, subject to the following:
  (a) for the purposes of identifying the appropriate wholesale mark-up formula in Step 2 of the methodology, the ex-manufacturer price for the relevant quantity is to be worked out proportionately from the approved ex-manufacturer price or proportional ex-manufacturer price for the pack quantity of the pharmaceutical benefit; and
  (b) otherwise, the methodology is to be applied as if the claimed price for the pack quantity of the pharmaceutical benefit were the approved ex-manufacturer price or proportional ex-manufacturer price for the pack quantity.

15 Charge for delivery

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.

16 Claims for payment

(1) 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.

(2) The Chief Executive Medicare must determine the amount payable for a claim made under this Part and make any payment relating to the claim.

(3) Despite section 99AAA of the Act, the association must submit its claims for the supplies it makes during a month on a form approved in writing by the Chief Executive Medicare for this section.

Note: Section 99AAA of the Act provides for rules to be made by the Minister about procedures for claims for payment.

17 Stock of pharmaceutical benefits etc.

An authorised association may:

(a) order a pharmaceutical benefit from:

(i) the responsible person for the brand of the pharmaceutical item in the pharmaceutical benefit; or

(ii) a wholesaler for the pharmaceutical benefit; and

(b) keep in stock at its premises an adequate supply of pharmaceutical benefits for supply to its members under this Special Arrangement.

18 Internal review of decisions

Application for review

(1) A person who is affected by a decision of the Chief Executive Medicare under this instrument may apply to the Secretary for review of the decision.

(2) An application for review must:

(a) be in writing; and

(b) be made within:

(i) 28 days after the day the decision first came to the notice of the applicant; or

(ii) if the Secretary allows a longer period (whether before or after the end of the 28-day period referred to in subparagraph (i))—that longer period.

Review of decision

(3) On receiving an application, the Secretary must:
  (a) review the decision; and
  (b) affirm, vary or set aside the decision; and
  (c) if the Secretary sets aside the decision—make a new decision in substitution for the decision set aside.

(4) The decision (the ***decision on review***) of the Secretary takes effect:
  (a) on the day specified in the decision on review; or
  (b) if a day is not specified—on the day the decision on review was made.

Notice of decision

(5) After the Secretary makes a decision under this section, the Secretary must give the applicant a written notice stating the following:
  (a) the terms of the decision;
  (b) the reasons for the decision.

19 Application of this Special Arrangement

This Special Arrangement applies to a supply of a pharmaceutical benefit that is made the day after registration.

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

(sections 5, 7 and 11)

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Maximum Amount
Bisacodyl	Tablet, 5mg	oral	Lax-Tab	AE	400
	Suppositories 10mg, 10	rectal	Dulcolax	VZ	9
			Petrus Bisacodyl Suppositories	PP	9
	Suppositories 10mg, 12	rectal	Petrus Bisacodyl Suppositories	PP	8
	Enemas 10mg in 5mL, 25	rectal	Bisalax	AS	2
Macrogol 3350	Sachets containing powder for oral solution 13.125g with electrolytes, 30	oral	APOHEALTH Macrogol with Electrolytes	GX	2
			APO-MACROGOL plus ELECTROLYTES	TX	2
			Chemists' Own Macrogol with Electrolytes	RW	2
			LaxaCon	EA	2
			Macrovic	RF	2
			Molaxole	GO	2
			Movicol	NE	2
	Powder for oral solution 510g	oral	OsmoLax	KY	1
Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Enemas 3.125g-450mg-45mg in 5mL, 12	rectal	Micolette	AE	4
Sterculia with Frangula Bark	Granules 620mg-80mg, per g, 500g	oral	Normacol Plus	NE	2

Schedule 2—Responsible Person Codes

(section 7)

Code	Responsible Person	Australian Business Number
AE	AFT Pharmaceuticals (AU) Pty Ltd	29 105 636 413
AS	Aspen Pharmacare Australia Pty Limited	51 096 236 985
EA	Amneal Pharmaceuticals Pty Ltd	11 163 167 851
GO	Mylan Health Pty Ltd	29 601 608 771
GX	Apotex Pty Ltd	52 096 916 148
KY	Key Pharmaceuticals Pty Ltd	21 001 215 130
NE	Norgine Pty Ltd	78 005 022 882
PP	Petrus Pharmaceuticals Pty Ltd	21 108 884 126
RF	Arrow Pharma Pty Ltd	35 605 909 920
RW	Arrow Pharma Pty Ltd	35 605 909 920
TX	Apotex Pty Ltd	52 096 916 148
VZ	Sanofi-aventis Healthcare Pty Ltd	43 076 651 959

Schedule 3—Repeals

National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010

1 The whole of the instrument

Repeal the instrument

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021 (PB 31 of 2021)	15 Mar 2021 (F2021L00235)	16 Mar 2021 (s 2(1) item 1)	
National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2021 (No. 1) (PB 66 of 2021)	30 June 2021 (F2021L00916)	1 July 2021 (s 2)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep LA s 48D
Schedule 1	
Schedule 1	am F2021L00916
Schedule 3	
Schedule 3	rep LA s 48C