Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006

Instrument 2006 No. R33 as amended

made under the

*Australian Participants in British Nuclear Tests (Treatment) Act 2006*

This compilation was prepared on 3 May 2012 taking into account amendments up to the Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006 (Under Co-payment Data Collection) Instrument 2012 (No. R21/2012) (F2012L00745)

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1. **Definitions**

In sections 1-3 of this instrument:

*Act* means the *Australian Participants in British Nuclear Tests (Treatment) Act 2006*.

*Repatriation Pharmaceutical Benefits Scheme* means the instrument referred to as the “approved pharmaceutical scheme” in section 4 of the *Act* as that instrument is incorporated in the *Act*.

2. **Commencement**

This instrument commences on the day after it is registered on the Federal Register of Legislative Instruments.

3. **Modification of the Repatriation Pharmaceutical Benefits Scheme**

The *Repatriation Pharmaceutical Benefits Scheme* is modified in accordance with the Schedule.
SCHEDULE

4. Title

retain, adding at the end:

(Australian Participants in British Nuclear Tests) 2006

Note: the purpose of this provision is to ensure a part of the Repatriation Pharmaceutical Benefits Scheme (RPBS) as incorporated in the Act is retained to ensure the RPBS is modified and not substituted.

5. All provisions other than the Title:

substitute:

Australian Participants in British Nuclear Tests (Treatment) Act 2006

Section 18

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Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006

1. The Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006 is authorised by, and subject to, section 18 of the Australian Participants in British Nuclear Tests (Treatment) Act 2006.

Purpose of the Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006


Part 1 — Interpretation

3. For the purposes of this Scheme, unless a contrary intention appears:

“Act” means the Australian Participants in British Nuclear Tests (Treatment) Act 2006.

“Approved Hospital Authority” means a hospital authority approved under section 94 of the National Health Act 1953 for the purposes of supplying Pharmaceutical Benefits;

“Approved Medical Practitioner” means a medical practitioner approved under section 92 of the National Health Act 1953 for the purposes of supplying Pharmaceutical Benefits;
“Authority Prescription Form” means the form approved under:
   (i) subregulation 13(2) of the National Health (Pharmaceutical Benefits) Regulations; or
   (ii) paragraph 14 of declaration No. PB 10 of 1993 made under subsection 85(2) of the National Health Act 1953;

“approved supplier” has the meaning given in Part VII of the National Health Act 1953;

“Commission” means the Repatriation Commission continued in existence by section 179 of the Veterans’ Entitlements Act 1986;

“Community Pharmacist” means:
   (a) a registered pharmacist approved for the purposes of section 90 of the National Health Act 1953 in charge of a community pharmacy; or
   (b) a registered pharmacist approved for the purposes of section 90 of the National Health Act 1953, being the manager of a registered Friendly Society Dispensary; or
   (c) an Approved Hospital Authority; or
   (d) an Approved Medical Practitioner;

“Department” means the Department of Veterans’ Affairs;

“Diagnostic Agents” means Agents intended to facilitate the determination of human disease and/or human physiological states;

“Drugs” or “Medicines” means “goods for therapeutic use” as defined for human use by the Therapeutic Goods Act 1989;

“Eligible Person” means a person eligible for treatment under the Act who, if one has been granted, holds a Repatriation Health Card - For Specific Conditions;

“Explanatory Notes” means the text entitled “Explanatory Notes” and the text entitled “RPBS Explanatory Notes” that is published in the document, Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners, having the International Standard Serial Number 1037-3667, and dated 1 February 2002, to the extent that that text is not inconsistent with this Scheme;

[Note: see attachment for date changes. This note is not part of this Instrument]
“Medical Practitioner” has the same meaning as “medical practitioner” has in the Health Insurance Act 1973;

“PBS” means the Pharmaceutical Benefits Scheme authorised under the National Health Act 1953;

“PBS Schedule” means the Schedule of Pharmaceutical Benefits constituted by determinations and declarations under Part VII of the National Health Act 1953 (the Act) — by the Minister who administers that Act — as those determinations and declarations are in force from time to time — and includes any such determination, as in force from time to time, the application of which has been varied under a regulation under the Act.

“Pharmaceutical benefits” has the same meaning as “pharmaceutical benefits” in section 4 of the Act;

“Repatriation Health Card - For Specific Conditions” means an identification card, or written authorisation, provided to a person eligible under section 7 of the Act for treatment, subject to the Treatment Principles (Australian Participants in British Nuclear Tests) 2006, for malignant neoplasia;

“RPBS Schedule” means the Schedule of Pharmaceutical Benefits prepared by the Department of Veterans’ Affairs, entitled “Repatriation Schedule of Pharmaceutical Benefits” and dated 1 February 2002;

[Note: see attachment for date changes. This note is not part of this Instrument]

“Scheme” means the Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006.

“Secretary” has the meaning given in Part 1 of the National Health Act 1953.

“Standard Prescription Form” means the form approved under paragraph 19(1)(a) of the National Health (Pharmaceutical Benefits) Regulations;

“Treatment Principles” means the written document prepared by the Repatriation Commission and approved by the Minister under section 16 of the Act and entitled: Treatment Principles (Australian Participants in British Nuclear Tests) 2006.

“VEA RPBS” means the instrument made by the Commission under section 91 of the VEA and entitled the Repatriation Pharmaceutical Benefits Scheme.

“VEA” means the Veterans’ Entitlements Act 1986.
Notification of certain matters in the Explanatory Notes

4. Where it is provided for the Department or the Commission to notify of certain matters, the publication of the Explanatory Notes shall be taken to constitute such notification to the extent that the Explanatory Notes are relevant and are not inconsistent with other notification given by the Department or the Commission.

Department to notify of certain matters as agent of the Commission

5. Where it is provided that the Department may notify of certain matters, the Department may only do so for and on behalf of the Commission, as its agent.

Part 2 — Prescribing of Benefits
Procedure by Medical Practitioners

Prior Approval

6. (a) The Commission may approve any matters requiring Prior Approval in respect of the treatment of an Eligible Person for malignant neoplasia; and

(b) Prior Approval must be sought, in advance, in accordance with an Authority Prescription Form.

Restrictions

7. Restrictions apply to the prescribing of certain items. These include:

(a) items — quantities and repeats: those listed in the RPBS Schedule or PBS Schedule;

(b) surgical appliances and other treatment aids: surgical appliances and other treatment aids provided under the Treatment Principles may not be prescribed unless specifically listed in the RPBS Schedule;

(c) admixtures: the following restrictions apply to admixtures:

(i) admixture of two or more ready-prepared items into a single combined form, or the addition of one or more supplementary ingredients to a ready-prepared item, is not recognised as a Pharmaceutical Benefit;

(ii) the extemporaneous prescribing of two or more official formulary preparations in a single combined form, or the addition of one or more supplementary ingredients to an official...
formulary preparation, is a recognised *Pharmaceutical Benefit*; and

(iii) where one or more of the components of a preparation specified in subsubparagraph (ii) are non-RPBS Schedule or non-PBS Schedule items, Prior Approval is required for their prescribing;

(d) **conformity with standards**: no drug or therapeutic substance shall be prescribed unless it conforms with:

(i) the specific or general standards as determined by the relevant Minister under the *Therapeutic Goods Act 1989*; or

(ii) the British Pharmacopoeia, the United States Pharmacopoeia, the European Pharmacopoeia, the Australian Pharmaceutical Formulary, or a prescribed Pharmacology text of international standing;

(e) **basis for prescribing**: the prescribing of therapeutic substances other than on the clinical diagnosis of a Medical Practitioner shall be invalid;

(f) **approval for therapeutic use**: it is invalid to prescribe:

(i) an item that is not approved for therapeutic use in the treatment of human illness by the relevant Commonwealth, State or Territory Government agencies, or

(ii) an item for use if it is not in accordance with the terms and conditions specified by the relevant Government agencies in approving the item as a therapeutic substance;

(g) **Prior Approval for non-conforming items**: any drug or medicine intended for use other than in conformity with the requirements in subparagraph (d) requires Prior Approval;

(h) **PBS Schedule restricted items**: the prescribing of PBS Schedule restricted items is to comply with the restrictions relating to the prescribing of such items as indicated in the PBS Schedule unless Prior Approval is obtained to prescribe otherwise;

(i) **RPBS Schedule restricted items**: the prescribing of RPBS Schedule restricted items under this Part is to comply with the restrictions relating to the prescribing of such items as indicated in the RPBS Schedule unless Prior Approval is obtained to prescribe otherwise;
(k) **Prior Approval for non-Schedule items**: the prescribing of an item not included in the RPBS Schedule or PBS Schedule requires Prior Approval.

**Prescribing provisions**

8. The PBS Schedule and RPBS Schedule are the primary references for the prescribing of *Pharmaceutical Benefits*.

**Application of PBS Schedule restrictions and RPBS Schedule restrictions**

9. Restrictions specified in the PBS Schedule and RPBS Schedule which limit supply of items to a particular class of person, or are reserved for specified purposes or require an authority to prescribe, apply unless Prior Approval is obtained to prescribe otherwise.

**Prescriptions to conform with State or Territory Law**

10. For a prescription to be recognised by the Commission it must conform with the provisions of State or Territory law except in so far as that law is inconsistent with this Scheme.

**Form of prescriptions**

11. Prescriptions are to conform with the conditions which the Department or the Commission from time to time notifies (including conditions which have been so notified under the *VEA RPBS* and in force as at the commencement of this instrument), and are to be:

   (a) written by Medical Practitioners on an Authority Prescription Form or Standard Prescription Form as the case requires; or

   (b) produced on a computer by a Medical Practitioner approved, under paragraph 19(1)(a) of the National Health (Pharmaceutical Benefits) Regulations, to use computer generated prescriptions, by the Secretary to the Department that administers the *National Health Act 1953*.

**When prescriptions are invalid**

12. A prescription is not a valid Pharmaceutical Benefit if the Medical Practitioner:

   (a) prescribes a Pharmaceutical Benefit for a person in respect of whom another prescription for the same benefit has been written on the same day by the same Medical Practitioner; or
(b) prescribes, on the one form, a Pharmaceutical Benefit that is a drug of addiction and another Pharmaceutical Benefit, and directs that the supply of either Pharmaceutical Benefit is to be repeated (but, if no repeats of either item are ordered, the prescription may be accepted provided that this is in accordance with the relevant State or Territory law); or

(c) prescribes a narcotic drug for the Medical Practitioner writing the prescription; or

(d) prescribes on a Standard Prescription Form an item not listed in the RPBS Schedule or PBS Schedule; or

(e) prescribes on a Standard Prescription Form a benefit in contravention of any of the restrictions set out in paragraph 7.

**Maximum quantity and repeats allowed**

13. The quantity and repeats for Scheduled items are to be confined to those specified in the RPBS Schedule or PBS Schedule. However, where inadequate, the Medical Practitioner may seek Prior Approval to prescribe a quantity greater, or a greater number of repeats, than the maximum listed in the RPBS Schedule or PBS Schedule.

**Prescribing outside the RPBS Schedule or PBS Schedule**

14. If a Medical Practitioner is of the clinical opinion that there are no therapeutic alternatives available in the RPBS Schedule or PBS Schedule for the treatment of an Eligible Person, the Medical Practitioner may seek Prior Approval from the Commission to prescribe an item not contained in those Schedules.

**Medical Practitioner subject to this Scheme**

15. Where a Medical Practitioner prescribes for an Eligible Person, the Medical Practitioner shall be subject to the terms and conditions of this Scheme and the Explanatory Notes.
Part 3 — Supply of Pharmaceutical Benefits

Supply of Pharmaceutical Benefits — Procedure by Community Pharmacists

16. A Community Pharmacist is required to supply a Pharmaceutical Benefit only in respect of a condition associated with malignant neoplasia and only upon the surrender of:

(a) a valid Standard Prescription Form; or

(b) a valid Authority Prescription Form; or

(c) a valid repeat authorisation form presented with a duplicate prescription in accordance with the requirements under the PBS;

provided that such documents are in accordance with State or Territory law, or this Scheme and the Explanatory Notes, and with any requirements which the Department or the Commission, from time to time, notifies (including those notified under the VEA RPBS and in force at the commencement of this instrument).

Substitution of lesser priced alternative brand of drug

17. Where a valid prescription, issued by a Medical Practitioner, prescribes a brand of drug listed on the PBS or RPBS Schedule, a Community Pharmacist may substitute, with the approval of the prescriber, a lesser priced alternative PBS or RPBS listed brand of the drug in lieu of the brand prescribed and shall endorse the original, duplicate and repeat authorisation accordingly.

Community Pharmacist to be satisfied as to entitlement

18. (a) A Community Pharmacist shall not supply a Pharmaceutical Benefit to a person on terms that are appropriate for the supply of a Pharmaceutical Benefit to a holder of a Repatriation Health Card - For Specific Conditions, unless the Community Pharmacist is satisfied that the person is entitled to receive the Pharmaceutical Benefit on those terms.

(b) Without limiting the generality of subparagraph (a), a Community Pharmacist may refuse to supply a Pharmaceutical Benefit to a person on terms that are appropriate for the supply of the Pharmaceutical Benefit to a holder of a Repatriation Health Card - For Specific Conditions, unless the person produces such a card to the Community Pharmacist that indicates that the person is entitled to receive the Pharmaceutical Benefit on those terms.
Dispensing of deleted items

19. Prescriptions, including repeat authorisations, for items deleted from the RPBS Schedule or PBS Schedule may not be dispensed as Pharmaceutical Benefits as from the date of effect of deletion, unless the prescriptions for the items comply with Prior Approval arrangements under this Part.

Use of forms as notified by the Department or the Commission

20. When supplying a Pharmaceutical Benefit under this Scheme a Community Pharmacist will use and issue such forms, as are notified by the Department or the Commission from time to time (including those notified under the VEA RPBS and in force at the commencement of this instrument), in the manner notified by the Department or the Commission (including the manner notified under the VEA RPBS and in force at the commencement of this instrument).

Financial responsibility

21. In respect of each Pharmaceutical Benefit provided under this Scheme, the Commonwealth will accept financial responsibility for all of the dispensed price but the amount that would be payable by the person if the person were a concessional beneficiary under the National Health Act 1953.

Refund in certain circumstances

22. Where:

(a) a Community Pharmacist charges an Eligible Person an amount in respect of the provision of a Pharmaceutical Benefit; and

(b) information indicating the person’s eligibility under this Scheme was not supplied to the Community Pharmacist; and

(c) the Commission is satisfied that, in the circumstances, the person should be treated as if the relevant information had been supplied,

the person is entitled to be paid by the Commonwealth an amount equal to any amount that the person paid that would not have been payable if the relevant information had been supplied.

Part 4 — Claims by Community Pharmacists

Lodgement of Claims by Community Pharmacists

24. Claims by Community Pharmacists under this Part shall be made in accordance with section 99AAA of the National Health Act 1953 as though references in that section, and in the rules made under that section which relate to the supply of...
and payment for Pharmaceutical Benefits under that Act and its Regulations, were references to the supply of, and payment for, Pharmaceutical Benefits, except that:

(a) prescriptions for the supply of Pharmaceutical Benefits under this Part shall be marked in the S section or S sections (as defined in those rules) with one or more serial numbers allotted in respect of each Pharmaceutical Benefit commencing at “R1” in each claim and continuing consecutively in respect of that claim;

(b) these prescriptions shall be collected into one bundle, separate to the four bundles provided for in those rules, with the prescriptions sorted into the order of the serial numbers allocated under subparagraph (a), with the least serial number at the top of the bundle; and

(c) the information to be provided to the Secretary to the Department that administers the National Health Act 1953, in respect of each supply of a Pharmaceutical Benefit shall include a Form Category (within the meaning of the schedule to those rules) with a value of “8” where the Pharmaceutical Benefit was supplied on an original authority prescription or “9” where the Pharmaceutical Benefit was supplied on a repeat authority prescription, and a Payment Category (within the meaning of that schedule) with a value of “4”.

Payment subject to compliance

25. Payment under this Scheme is subject to compliance with paragraph 24.

Part 5 — Payments to Community Pharmacists

Dispensing fee payable to Community Pharmacists

26. The dispensing fee payable to Community Pharmacists (excluding Approved Medical Practitioners and Approved Hospital Authorities) for the supply by them, under this Scheme, of Pharmaceutical Benefits in the form of ready prepared items or of extemporaneously prepared items, shall be the fee payable to pharmacists under the PBS for the supply by them of a pharmaceutical benefit of similar form.

Dispensing fee payable to Approved Medical Practitioners and Approved Hospital Authorities

27. The dispensing fee payable to Approved Medical Practitioners and Approved Hospital Authorities for the supply by them, under this Scheme, of Pharmaceutical Benefits, in the form of ready prepared items or of extemporaneously prepared items, shall be the fee payable to Approved Medical Practitioners or Approved Hospital Authorities, under the PBS for the supply by them of a pharmaceutical benefit of similar form.
Other Fees — similar PBS pharmaceutical benefit

28. Where a Pharmaceutical Benefit is provided which is not covered by paragraphs 26 or 27, payment is to be made in accordance with the fee payable under the PBS for provision of a similar pharmaceutical benefit.

Other Fees — notified rates

29. Where a Pharmaceutical Benefit is provided which is not covered by paragraphs 26, 27 or 28, payment is to be made in accordance with such conditions and at such rates as the Department or the Commission from time to time notifies (including any rate in force at the commencement of this Instrument).

Fees not payable in some circumstances

30. The fees payable under paragraphs 26, 27, 28 or 29, may not be payable to a Community Pharmacist where that person does not satisfy the requirements of paragraph 18 and supplies Pharmaceutical Benefits to an ineligible person.

Community Pharmacist not entitled to demand or receive payments

31. A Community Pharmacist is not entitled to demand of, or receive from, a person in receipt of a Pharmaceutical Benefit, payment in money or a valuable consideration for goods and services rendered under this Scheme except:

   (a) for goods or services that are provided in an emergency; or
   (b) for payment of an after-hours fee; or
   (c) for payment for packaging material, postage or freight; or
   (d) for payment that represents the required payment under the PBS of the price difference between the drug prescribed and supplied and the lowest priced brand of the same drug listed on the PBS Schedule; or
   (e) where payment represents the difference between the Commonwealth’s financial responsibility for the provision of the Pharmaceutical Benefit and the dispensed price of the Pharmaceutical Benefit supplied.

Community Pharmacist to issue receipt where certain payments received

32. Where a payment is received, under any of subparagraphs 31(a), (b), (c) or (d), from a person in receipt of a Pharmaceutical Benefit, the Community Pharmacist is required to issue that person an official receipt which states:

   (a) the goods and/or services provided; and
(b) the date of receipt of those goods and/or services by the person.

Part 5A — Under Co-payment Data Collection

32A. Giving information

(1) A Community Pharmacist who gives information to the Secretary in relation to the supply, under the Scheme, of a Pharmaceutical benefit by the pharmacist to an Eligible Person, is taken to have given that information under, and for the purposes of, the Scheme, provided that:

(a) no claim for payment is made by the Community Pharmacist on the Commission or Department for dispensing the Pharmaceutical benefit; and

(b) the dispensing price of the pharmaceutical benefit is less than, or equal to, the co-payment that would have been paid by the Eligible Person for the pharmaceutical benefit if it had been dispensed at a price for which a co-payment is payable; and

(c) the information is given in accordance with the requirements, to the extent applicable, that apply under section 98C of the National Health Act 1953 to an approved supplier giving information to the Secretary in relation to the supply to a person of a pharmaceutical benefit, as if references in section 98C to an approved supplier and a pharmaceutical benefit are references to, respectively, a Community Pharmacist and a Pharmaceutical benefit and the pharmaceutical benefit has been supplied under the Scheme.

Note: a Community Pharmacist includes an Approved Hospital Authority.

Part 6 — Miscellaneous

Standards

33. The minimum acceptable standard for a Pharmaceutical Benefit is that described in the following documents:

(a) the British Pharmacopoeia or the Pharmaceutical Codex as amended and authorised by regulations under the Therapeutic Goods Act 1989;

(b) the regulations under the Therapeutic Goods Act 1989 which relate to specific standards for drugs;
(c) the Australian Pharmaceutical Formulary which describe drugs and medicinal preparations;

(d) previous editions of the British Pharmacopoeia, Pharmaceutical Codex or the Australian Pharmaceutical Formulary which describe drugs and medicinal preparations; and

(e) the Extra Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopoeia or similar pharmaceutical texts of international standing which describe drugs.

Editions of monographs and standards

34. The monographs and standards contained in the latest authorised editions of the documents listed in paragraph 33 take precedence over earlier editions unless a specific edition is specified.

Order of precedence

35. The order of precedence for drug monographs and standards is in the same order as set out in paragraph 33, with the monographs of the British Pharmacopoeia having precedence over all others and thereafter in accordance with State or Territory law.

Discretionary powers

36. In order to expedite the processing of claims and to facilitate the efficient management of this Scheme, the Commission may vest in Community Pharmacists acting in good faith such discretionary powers, as it from time to time notifies, to make specified adjustments and/or endorsements to prescriptions and/or repeat authorisations forms. Such discretionary powers may be exercised notwithstanding anything else contained in this Scheme.

Retention of Documents

37. A Community Pharmacist is to retain such documents and keep such records as the Department or the Commission from time to time notifies.

Agreement with the Pharmacy Guild of Australia

38. The Commission may enter into agreements concerning the administration of this Part with the Pharmacy Guild of Australia and, subject to this Part, shall abide by such agreements.

39. In the event the Commission does not enter into an agreement under paragraph 38, any agreement between the Commission and the Pharmacy Guild of Australia
made for the purposes of paragraph 38 of the VEA RPBS applies under this Scheme as if made for the purposes of this Scheme.
Notes to the Repatriation Pharmaceutical Benefits Scheme (Australian Participants in British Nuclear Tests) 2006

Note 1


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