EXPLANATORY STATEMENT

Veterans' Affairs (Extending Medication Chart Prescribing to Hospitals and Other Measures) Instrument 2015

EMPOWERING PROVISIONS

Subsection 91(3) of the *Veterans' Entitlements Act 1986* (the VEA). Subsection 286(3) of the *Military Rehabilitation and Compensation Act 2004* (MRCA).

PURPOSE

The attached instrument (2015 No. R1/MRCC1), varies:

- in Schedule 1 the *Repatriation Pharmaceutical Benefits Scheme* under the VEA;
- in Schedule 2 the MRCA Pharmaceutical Benefits Scheme under the MRCA;

(collectively referred to as "the Schemes").

The Schemes are legislative instruments and set out the circumstances in which the Repatriation Commission and the Military Rehabilitation and Compensation Commission (the Commissions) may arrange for pharmaceutical benefits to be provided to veterans, members (including former members) of the Defence Force, or their dependants (collectively referred to as "eligible person") at a concessional rate.

The Repatriation Pharmaceutical Benefits Scheme applies, subject to modifications, to people entitled to treatment under the Australian Participants in British Nuclear Tests (Treatment) Act 2006 (see s.18 of that Act).

The attached instrument has two purposes:

- to enable the type of pharmaceutical prescribing known as "medication chart prescribing" to be used in relation to patients in hospital (main purpose of the attached instrument)
- to tighten up provisions relating to "incorporated documents" to ensure the descriptions of the documents are adequate.

medication chart prescribing

Prior to the attached instrument, medication chart prescribing was only relevant to the prescription of pharmaceuticals for residents of aged care facilities. The attached instrument enabled medication chart prescribing to also be used for patients in hospital.

Medication chart prescribing works as follows. Residents in aged care facilities (residents) or patients in hospital (patients) receiving medication have a medication chart showing the medicines the person receives.

A medical practitioner inserts relevant information in an item in the chart. Essentially an item in the Medication Chart, that is completed in accordance with the Schemes, is a prescription for the purposes of the Schemes. A copy of the chart is provided to a pharmacist i.e. it is the prescription.

The advantages of this method of prescribing is that "transcription errors" may be reduced, as there is one medication management resource for residents/patients for most of their medicines. Further the prescriber does not need to write prescriptions at a later time once they have returned from their visit to the facility/hospital, which may prevent transcription error due to recall error. This would not only reduce the administrative burden for pharmacists in following up discrepancies, but would also improve resident/patients medication safety.

Also, access by the pharmacist to the prescriber's ongoing order for supply from the medication chart means the risk of disruption to the resident's/patient's ongoing therapy is reduced.

A trial of medication chart prescribing in 20 or so selected residential care facilities in NSW in 2013 proved successful in the context of aged care residents. The Department of Health is now overseeing the trial of medication chart prescribing for hospital patients. The trial is for a two year period.

Accordingly, medication chart prescribing for hospital patients under the Schemes is currently only permitted in the situations covered by the trial being managed by the Department of Health i.e. in hospitals approved for medication chart prescribing by the Minister for Health under the *National Health (Pharmaceutical Benefits) Regulations 1960* (national health regulations).

The Schemes needed to be varied for the purposes of the trial because a patient of a hospital may be an eligible person (veteran etc) and a medical practitioner may, during the trial, seek to prescribe a medicine for the person via a medication chart but the medicine is being prescribed under the Schemes and not the Pharmaceutical Benefits Scheme under the *National Health Act 1953*.

CONSULTATION

Yes, for the variations that relate to the Medication Chart. The Department of Health (DoH) was consulted. The DoH is the agency managing the extension of medication chart prescribing to hospital patients.

Noting that paragraph 26(1A)(d) of the *Legislative Instruments Act 2003* requires an Explanatory Statement for a legislative instrument to contain a description of the nature of any consultation, the nature of the consultation for the proposal in question was by way of electronic mail.

No, for the variations that relate to incorporated documents because they are minor and technical

RETROSPECTIVITY

None.

Human Rights Compatibility

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

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

The attached legislative instrument does engage an applicable right or freedom. It relates to the Right to Health contained in article 12(1) of the International Covenant on Economic Social and Cultural Rights.

The Right to Health is the right to the enjoyment of the highest attainable standard of physical and mental health. The UN Committee on Economic Social and Cultural Rights has stated that health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.

The attached legislative instrument engages with, and promotes, the Right to Health. The health initiative introduced by the instrument could benefit the health of the relevant people in hospital by enabling their medications to be better managed.

The instrument does impose certain conditions relating to the use of the medication chart prescription. The UN Committee on Economic Social and Cultural Rights has stated that qualifying conditions for benefits must be reasonable, proportionate and transparent.

In this case the conditions are more safeguards than restrictions on the availability of a benefit e.g. in order for a medicine to be properly dispensed on the basis of a medication chart, the pharmacist's approval number must be written in the copy of the medication chart in the pharmacist's possession.

Conclusion

The attached legislative instrument is considered to be compatible with the human right to health because it promotes the right to health. It extends a type of prescribing of pharmaceutical benefits (medication chart prescribing) that aids medication management to people in hospital, and the conditions it imposes on the use of medication chart prescribing are considered reasonable in the circumstances because they are in the nature of supervisory safeguards.

Michael Ronaldson Minister for Veterans' Affairs Rule-Maker

DEREGULATION

The attached instrument is regulatory. It imposes compliance-requirements on prescribers who seek to use the medication chart prescription for hospital patients.

Extending medication chart prescribing to patients in hospital is a Department of Health (DoH) initiative. DVA followed the DoH's lead in the matter and the two exercises were implemented in tandem. In these circumstances consulting interested parties and assessing the regulatory impact of the proposal was the responsibility of the DoH.

FURTHER EXPLANATION

See: Attachment A

Attachment A

Section 1

This section sets out the name of the instrument - the *Veterans' Affairs (Extending Medication Chart Prescribing to Hospitals and Other Measures) Instrument 2015.*

Section 2

This section is a commencement provision and provides that the instrument commences on 1 April 2015, which is the same date relevant amendments to the national health regulations commence.

Section 3

This section is a transitional provision and makes it clear that the variations to the Schemes made by the instrument apply only to prescriptions written on or after the commencement of the instrument.

Sections 4 and 5

These sections are application provisions and their effect is to confine medication chart prescribing for patients in hospitals under the Schemes to those hospitals approved by the Minister for Health under the national health regulations for the purposes of the relevant trial.

Sections 4 and 5 will be revoked when the provisions in the national health regulations that confine medication chart prescribing in hospitals to certain approved hospitals, are revoked i.e. the trial is completed. Medication chart prescribing will then be permitted for patients in a hospital in respect of which the hospital authority is approved under section 94 of the *National Health Act 1953*.

Schedule 1 - Variations to the Repatriation Pharmaceutical Benefits Scheme (the RPBS or the Scheme)

Item 1

This item is a definitions section. An important new definition is the definitions of the "claims rules" (claim rules under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*) as the claims rules, and not the Scheme, now regulate <u>in detail</u> the provision of supply certification forms for claims for payment from Community Pharmacists (the claims rules being incorporated-by-reference into the Scheme).

Item 2

This item is a definitions section. An important revised definition is the definition of "supply certification form". This form is now defined by reference to the claim rules in force from time to time under the *National Health Act 1953*.

This item also better identifies certain documents incorporated-by-reference into the Scheme. Thus the item defines the "Explanatory Notes" to mean those parts of the document known as the "Pharmaceutical Benefits Scheme" (PBS) that are called "Section 1 – Explanatory Notes" and "RPBS Explanatory Notes". These parts of the PBS are incorporated-by-reference into the Scheme and are to be regarded as distinct documents for the purpose of incorporation.

This item revises the definitions of other incorporated documents, namely: "PBS", "Pharmaceutical Benefits Scheme" and "RPBS Schedule" and, as with the definition Explanatory Statement to F2015L00376

of Explanatory Notes, identifies the documents for the purpose of incorporation into the Scheme.

Item 3

This item replaces section 4 in essentially the same terms as the previous section 4 but better identifies the documents that are to be taken as containing the relevant notification under the Scheme.

New section 4 provides that where, under the Scheme, the Department of Veterans' Affairs, or the Repatriation Commission, may give a notice about a particular matter, the giving of the notice is taken to have occurred if the matter is included in the RPBS Explanatory Notes and published as part of the publication of the Pharmaceutical Benefits Scheme.

Item 4

This item is a drafting variation.

Item 5

This item introduced a new section 11AA based on the similar provision in the national health regulations. Section 11AA indicates the provisions in the Scheme that cover the writing of prescriptions and establishes the basis for the Scheme distinguishing between prescriptions that are not medication chart prescriptions and prescriptions that are.

This item also introduced a new section 11A based on the similar provision in the national health regulations. The Scheme previously incorporated-by-reference the "prescribing provisions" in the national health regulations and still does in a general way but it was incongruous to prescribe medication chart prescribing in detail in the Scheme and not have the similar level of detail for non-medication chart prescribing. Accordingly the relevant parts of the national health regulations that cover non-medication chart prescribing and which were previously incorporated-by-reference in the Scheme have now been set out in the Scheme in section 11A.

This item also introduced a revised "medication chart prescribing provision" (section 11B) which is essentially the same as the previous provision except that it now covers medication chart prescribing for patients in hospital whereas previously it only covered residents receiving a residential care service.

Item 6

This item omitted the section (11C) that related to the supply certification form because the form is now regulated under the "claims rules" ("claims rules" are rules in force from time to time made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*) and are incorporated-by-reference into the Scheme.

Item 7

This item replaced a note that gave a general description of medication chart prescribing. The new note is in similar terms except that it recognises that medication chart prescribing could now occur for hospital patients in addition to people in residential care.

The note reflects the principle in the Scheme that a person can only be prescribed a medicine under the Scheme using a medication chart prescription if the prescription could have been used for the person under the *National Health (Pharmaceutical*

Benefits) Regulations 1960 as if the medicine was listed on the Pharmaceutical Benefits Scheme.

Because medication chart prescribing can only be used in certain situations (residential care/hospital), including a trial situation where medication chart prescribing for people in hospital is concerned, the intention is to confine such prescribing under the Scheme to those situations.

Item 8

This item introduces section 16AA which is the former section 24B. Former section 24B had been positioned in the wrong place in the Scheme. It deals with supply by Community Pharmacists but had been placed in the part of the Scheme that deals with claims by Community Pharmacists. The new aspect of section 16AA is the application of the provision to the supply of a pharmaceutical benefit pursuant to a medication chart prescription for a person in hospital. Apart from that change, the provision is the same as the former section 24B.

Item 9

This item inserts new section 16AB which is based on a similar provision in the national health regulations. Section 16AB sets out information about concessionary card holders etc that a Community Pharmacist must include in a claim for payment when claiming for a supply of a pharmaceutical benefit pursuant to a medication chart prescription or continued dispensing (see section 16A of the Scheme).

Item 10

This item omitted section 24A because the matter it covered (claims by community pharmacists in respect of the supply of a pharmaceutical benefit pursuant to a medication chart prescription) is covered by section 24 i.e. section 24A was unnecessary.

Item 11

This item inserted notes at the end of section 24. This section makes provision for claims for payment under the Scheme.

Note 1 advises that paragraph 24 incorporates-by-reference into the Scheme the various rules in and under the *National Health Act 1953* in relation to claims for payment for the supply of medicines under the *National Health Act 1953*. In particular the requirements for claims under the "claims rules" (rules in force from time to time made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*) apply to claims for payment under the Scheme.

Note 2 advises that if a claim for payment is made electronically, the claims rules require the supply certification form (the form that certifies the supply of medicines) to be given electronically.

Note 3 advises that the claims rules provide that for electronic claims for payment, the claimant need not submit prescriptions with the claim.

Item 12

This item omits section 24B because it was in the wrong place in the Scheme. Section 24B has been re-cast as section 16AA (see Item 8 above).

Item 13

This item substituted section 25. Section 25 is essentially the same as the previous section 25 save that the previous paragraph 25(2) has been omitted and subsumed in paragraph 25 generally. Further, paragraph 25 has been extended in scope to explicitly require all claims for payment under the Scheme to be accompanied by a supply certification form, not just claims based on medication chart prescriptions.

Item 13A

This item substituted section 37. Section 37 is essentially the same as the previous section 37 save that an anomaly in relation to the indexing base of the pharmaceutical allowance for the war widow/war widower pension has been rectified. Previously the indexing base was section 198 of the *Veterans' Entitlements Act 1986* (VEA) when it should have been the same as the indexing base for the Pension Supplement under Division 18 of Part IIIB of the VEA.

Further, some indexing references in the section have been tightened as follows:

- for Pharmaceutical Allowance for veterans supplement in section 198F of the VEA, the allowance is to be indexed as if it is the "dollar amount" (i.e. veterans supplement) in 198F(1).
- for Pharmaceutical Allowance for payments indexed under Division 18 of Part IIIB of the VEA, the allowance is to be indexed as if it is Pension Supplement in Item 1A of CPI Indexation Table in section 59B of the VEA.

Item 14

This item introduces three new sections (45, 45A and 45B) to cover the matter covered by the former section 45 (keeping of documents). These new sections collectively represent an updated version of the previous section 45 – updated to reflect changes made to similar provisions in the national health regulations.

Item 15

This item more accurately describes the process of incorporating certain documents into the Scheme. Instead of referring to the documents as in force on a particular date, which implies the documents are legislative (which they are not), the new provision refers to the relevant documents as they exist on a particular date.

Item 16

This item more accurately identifies certain documents incorporated-by-reference into the Scheme. The documents being incorporated are the documents defined in the Scheme by the terms in question. For example, the RPBS Explanatory Notes is the document defined in the Scheme as the RPBS Explanatory Notes.

Schedule 2 - Variations to the MRCA Pharmaceutical Benefits Scheme (MPBS or the Scheme)

Item 1

This item is a definitions section. An important new definition is the definitions of the "claims rules" (claim rules in force from time to time under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*) as the claims rules, and not the Scheme, now regulate <u>in detail</u> the provision of supply certification forms for claims for payment from Community Pharmacists (the claims rules being incorporated-by-reference into the Scheme).

Item 2

This item is a definitions section. An important revised definition is the definition of "supply certification form". This form is now defined by reference to the claim rules in force from time to time under the *National Health Act 1953*

This item also better identifies certain documents incorporated-by-reference into the Scheme. Thus the item defines the "Explanatory Notes" to mean those parts of the document known as the "Pharmaceutical Benefits Scheme" (PBS) that are called "Section 1 – Explanatory Notes" and "RPBS Explanatory Notes". These parts of the PBS are incorporated-by-reference into the Scheme and are to be regarded as distinct documents for the purpose of incorporation.

This item revises the definitions of other incorporated documents, namely: "PBS", "Pharmaceutical Benefits Scheme" and "RPBS Schedule" and, as with the definition of Explanatory Notes, identifies the documents for the purpose of incorporation into the Scheme.

Item 3

This item replaces section 4 in essentially the same terms as the previous section 4 but better identifies the documents that are to be taken as containing the relevant notification under the Scheme.

New section 4 provides that where, under the Scheme, the Department of Veterans' Affairs, or the Military Rehabilitation and Compensation Commission, may give a notice about a particular matter, the giving of the notice is taken to have occurred if the matter is included in the RPBS Explanatory Notes and published as part of the publication of the Pharmaceutical Benefits Scheme.

Item 4

This item is a drafting variation.

Item 5

This item introduced a new section 11AA based on the similar provision in the national health regulations. Section 11AA indicates the provisions in the Scheme that cover the writing of prescriptions and establishes the basis for the Scheme distinguishing between prescriptions that are not medication chart prescriptions and prescriptions that are.

This item also introduced a new section 11A based on the similar provision in the national health regulations. The Scheme previously incorporated-by-reference the "prescribing provisions" in the national health regulations and still does in a general

way but it was incongruous to prescribe medication chart prescribing in detail in the Scheme and not have the similar level of detail for non-medication chart prescribing. Accordingly the relevant parts of the national health regulations that cover non-medication chart prescribing and which were previously incorporated-by-reference in the Scheme have now been set out in the Scheme in section 11A.

This item also introduced a revised "medication chart prescribing provision" (section 11B) which is essentially the same as the previous provision except that it now covers medication chart prescribing for patients in hospital whereas previously it only covered residents receiving a residential care service.

Item 6

This item omitted the section (11C) that related to the supply certification form because the form is now regulated under the "claims rules" ("claims rules" are rules in force from time to time made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*).

Item 7

This item replaced a note that gave a general description of medication chart prescribing. The new note is in similar terms except that it recognises that medication chart prescribing could now occur for hospital patients in addition to people in residential care.

The note reflects the principle in the Scheme that a person can only be prescribed a medicine under the Scheme using a medication chart prescription if the prescription could have been used for the person under the *National Health (Pharmaceutical Benefits) Regulations 1960* in force from time to time as if the medicine was listed on the Pharmaceutical Benefits Scheme.

Because medication chart prescribing can only be used in certain situations (residential care/hospital), including a trial situation where medication chart prescribing for people in hospital is concerned, the intention is to confine such prescribing under the Scheme to those situations.

Item 8

This item introduces section 16AA which is the former section 24B. Former section 24B had been positioned in the wrong place in the Scheme. It deals with supply by Community Pharmacists but had been placed in the part of the Scheme that deals with claims by Community Pharmacists. The new aspect of section 16AA is the application of the provision to the supply of a pharmaceutical benefit pursuant to a medication chart prescription for a person in hospital. Apart from that change, the provision is the same as the former section 24B.

Item 9

This item inserts new section 16AB which is based on a similar provision in the national health regulations. Section 16AB sets out information about concessionary card holders etc that a Community Pharmacist must include in a claim for payment when claiming for a supply of a pharmaceutical benefit pursuant to a medication chart prescription or continued dispensing (see section 16A of the Scheme).

Item 10

This item omitted section 24A because the matter it covered (claims by community pharmacists in respect of the supply of a pharmaceutical benefit pursuant to a

medication chart prescription) is covered by section 24 i.e. section 24A was unnecessary.

Item 11

This item inserted notes at the end of section 24. This section makes provision for claims for payment under the Scheme.

Note 1 advises that paragraph 24 incorporates-by-reference into the Scheme the various rules in and under the *National Health Act 1953* in relation to claims for payment for the supply of medicines under the *National Health Act 1953*. In particular the requirements for claims under the "claims rules" (rules in force from time to time made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*) apply to claims for payment under the Scheme.

Note 2 advises that if a claim for payment is made electronically, the claims rules require the supply certification form (the form that certifies the supply of medicines) to be given electronically.

Note 3 advises that the claims rules provide that for electronic claims for payment, the claimant need not submit prescriptions with the claim.

Item 12

This item omits section 24B because it was in the wrong place in the Scheme. Section 24B has been re-cast as section 16AA (see Item 8 above).

Item 13

This item substituted section 25. Section 25 is essentially the same as the previous section 25 save that the previous paragraph 25(2) has been omitted and subsumed in paragraph 25 generally. Further, paragraph 25 has been extended in scope to explicitly require all claims for payment under the Scheme to be accompanied by a supply certification form, not just claims based on medication chart prescriptions.

Item 13A

This item substituted section 37. Section 37 is essentially the same as the previous section 37 save that some indexing references in the section have been tightened as follows:

- for Pharmaceutical Allowance for veterans supplement in section 198F of the VEA, the allowance is to be indexed as if it is the "dollar amount" (i.e. veterans supplement) in 198F(1).
- for Pharmaceutical Allowance for payments indexed under Division 18 of Part IIIB of the VEA, the allowance is to be indexed as if it is Pension Supplement in Item 1A of CPI Indexation Table in section 59B of the VEA.

Item 14

This item introduces three new sections (45, 45A and 45B) to cover the matter covered by the former section 45 (keeping of documents). These new sections collectively represent an updated version of the previous section 45 – updated to reflect changes made to similar provisions in the national health regulations.

Item 15

This item more accurately describes the process of incorporating certain documents into the Scheme. Instead of referring to the documents as in force on a particular date,

which implies the documents are legislative (which they are not), the new provision refers to the relevant documents as they exist on a particular date.

Item 16

This item more accurately identifies certain documents incorporated-by-reference into the Scheme. The documents being incorporated are the documents defined in the Scheme by the terms in question. For example, the RPBS Explanatory Notes is the document defined in the Scheme as the RPBS Explanatory Notes.

Item 17

This item provides that all references in the Scheme to "RPBS prescriber" are to be replaced with references to "MPBS prescriber" i.e. a prescriber under the MRCA Pharmaceutical Benefits Scheme, because it is more appropriate.