EXPLANATORY STATEMENT

Veterans' Entitlements Act 1986 Military Rehabilitation and Compensation Act 2004

Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020

Authority

Subsection 286(5) of the *Military Rehabilitation and Compensation Act 2004* (the MRCA) and subsection 91(4) provide that the Military Rehabilitation and Compensation Commission and the Repatriation Commission respectively may vary the *MRCA Pharmaceutical Benefits Scheme* (MRCA PBS) and the *Repatriation Pharmaceutical Benefits Scheme* (RPBS) (also referred to as the Schemes).

The proposed changes to the Schemes are to implement a measure made as part of the COVID-19 National Health Plan. One of the measures concerns the introduction of temporary Medicare Benefits Schedule (MBS) items to allow doctors, nurses, midwives and mental health professionals to deliver services via telehealth, provided those services are bulk billed.

The temporary MBS items have also been incorporated into the Fee Schedules that apply for the purposes of the Treatment Principles in order to provide telehealth services to those persons eligible for treatment under Veterans' Affairs portfolio Acts.

Purpose

The proposed instrument, made under subsections 286(5) of the MRCA and 91(4) of the VEA, ensures that DVA clients eligible for pharmaceutical benefits under the Schemes will also benefit from the implementation of the telehealth measures that form part of the COVID-19 National health Plan.

The proposed instrument amends the Schemes to incorporate (as modified by the amendments to the Schemes), the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the National Health Act instrument) as in force from time to time.

The incorporation of the legislative instrument on that basis is provided for under paragraph 14(1)(b) of the *Legislation Act 2003*.

Part of the COVID-19 National Health Plan provides for temporary MBS items to deliver health services via telehealth and telephone. The arrangements are described as set out in the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020.*

The National Health Act instrument (defined in section 3 of the Schemes as the 'special arrangement') has been developed by the Department of Health under Section 100 of the *National Health Act 1953* to implement interim measures that provide patients who are confined to their homes with access to necessary medicines through a measure referred to as 'Image Based Prescription for Medicine Supply'.

As stated, it is an interim measure and the instrument includes a provision for it to be repealed (under section 4) at the start of 30 September 2020.

Under the special arrangement prescribers and patients are allowed to provide a pharmacy with a digital image of their prescription via fax, email or text message, enabling the pharmacy to dispense their medicines, and deliver or post them to the patient.

As incorporated in to the Schemes, the 'special arrangement' is restricted to those patients who are vulnerable and have had a telehealth consultation as described at the *Health Insurance (Section 3C General Medical Services – COVID-19 Telehealth and Telephone Attendances) Determination 2020.*

The exception to this is a patient who is self-isolating and has an existing prescription issued prior to self-isolation and not part of the telehealth measure eg. a repeat. In those circumstances the patient may create an image of the prescription and forward it to the pharmacy of their choice to gain supply.

The 'special arrangement' applies to all pharmaceutical benefits available for supply under the Schemes other than the exceptions listed in paragraphs 7(1)(a) and (b) of the National Health Act instrument. Those paragraphs refer to medicines listed in the Schedules to the *Poisons Standard* such as opioids and Fentanyl which are high-risk medicines that pose significant risks to the community including misuse and diversion.

The Department of Health have advised that pharmacists have also raised concerns surrounding the PBS requirement for patients (or a nominated agent) to sign the prescription to acknowledge receipt of supply of a pharmaceutical benefit due to potential contamination risks of people in the pharmacy using pens to sign for this purpose in the current COVID-19 environment.

The National Health Act instrument includes a provision which temporarily allows the supply of a pharmaceutical benefit without acknowledgement from the patient wherever it is impractical for them to sign the prescription (eg. where the patient is concerned about transmission of COVID-19 by using the pharmacy pen) until the cessation of the MBS Telehealth measures under the COVID-19 National Health Plan.

Community pharmacists are still expected to ask patients to acknowledge receipt of the pharmaceutical benefit where practical, however pharmacists are not required to sign on the patient's behalf where it is not practical do so (e.g. the pharmacist suppling medicine from an image based prescription). This measure should be used as an exception, not a rule, and pharmacists are required to use their professional judgement in these circumstances and implement localised processes for vulnerable patients.

The amendments to the Schemes to incorporate the 'special arrangement' ensure that eligible DVA clients will be able to obtain pharmaceutical benefits under the Schemes on the same basis as persons eligible for pharmaceutical benefits under the general Pharmaceutical Benefits Scheme (PBS).

The Department of Health have advised that the 'special arrangement' will be repealed on 30 September 2020 in line with the repeal of the Telehealth measures.

There is provision to extend the special arrangement if the telehealth measures are extended past 30 September 2020.

The National Health Act instrument as incorporated for the Schemes does not override state and territory laws.

Consultation

The proposed instrument affects community pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit.

The Department of Health has advised that it has consulted with clinical peak bodies and industry regarding the requirement for an interim measure prior to the implementation of Fast Track Electronic Prescribing.

The Department of Health has consulted with DVA and contacted the Department of Human Services and state and territory governments through the Electronic Prescribing Working Group (EPWG) about the special arrangement.

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

Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020 (Instrument 2020 No. R13/MRCC13)

1 Name

This section provides that the proposed instrument is the *Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020.*

2 Commencement

This section states that the instrument commences on the day after it is registered.

3 Authority

This section states that this instrument is made under section 286 of the *Military Rehabilitation and Compensation Act 2004* and section 91 of the *Veterans' Entitlements Act 1986*.

4 Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

MRCA Pharmaceutical Benefits Scheme

Item 1 inserts a definition of 'special arrangement' into section 3 of the MRCA PBS defining it as the instrument made by the Minister for Health under section 100 of the *National Health Act 1953*, the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the National Health Act instrument) which modifies the arrangements for the supply of pharmaceutical benefits under Part VII of the *National Health Act 1953*.

Item 2 makes a consequential amendment to section 16 of the MRCA PBS to include a reference to new section 16AAA (inserted by item 3) which provides for the provision of pharmaceutical benefits under a 'special arrangement'.

Section 16 provides for the procedures to be followed by a community pharmacist in the ordinary supply of pharmaceutical benefits. The inclusion of the reference to section 16AAA provides with section 16A (continued dispensing) for exceptions to the ordinary supply.

Item 3 inserts new section 16AAA into the MRCA PBS. Section 16AAA provides for the conditions that must apply for the supply of pharmaceutical benefits under the MRCA PBS by a community pharmacist in the circumstances where the 'special arrangement' as defined in section 3 is in place.

The conditions as set out in subsection 16AAA(1) are:

- the supply must be made in accordance with the conditions specified in the National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020 (the National Health Act instrument) as if the supply under the MRCA PBS is a supply covered by that instrument; and
- the National Health Act instrument has effect as modified by the provisions set out in new section 16AAA to the extent that those conditions are applicable to the supply; and
- the supply occurs before the repeal of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*; and
- the supply otherwise conforms with the requirements of section 16AAA.

New subsection 16AAA(2) includes a Table which modifies certain references in the National Health Act instrument by replacing them with terms used in the MRCA PBS for the purposes of supplying pharmaceutical benefits under new subsection 16AAA(1).

New subsection 16AAA(3) provides that for the purposes of the MRCA PBS the definition of 'approved hospital authority' in the National Health Act instrument is omitted.

New subsection 16AAA(4) provides that for the purposes of the MRCA PBS, the definition of 'approved hospital authority dispenser' in the National Health Act instrument will mean the community pharmacist or approved medical practitioner who has or who has supervised the dispensing of a pharmaceutical benefit supplied by an Approved Hospital Authority.

New subsection 16AAA(5) provides that for the purposes of the MRCA PBS the definition of 'CTS claim' in the National Health Act instrument is omitted.

New subsection 16AAA(6) provides that for the purposes of the MRCA PBS, the definition of 'medical chart prescription' in the National Health Act instrument will have the same meaning as it does in the MRCA PBS.

New subsection 16AAA(7) provides that for the purposes of the MRCA PBS, the definition of 'paper-based prescription' in the National Health Act instrument will have the same meaning as it does in the MRCA PBS.

New subsection 16AAA(8) replaces for the purposes of the MRCA PBS, section 8 of the National Health Act instrument.

Section 8 of the National Health Act instrument states that a provision of Part VII of the *National Health Act 1953*, or regulations and legislative instruments that are made for the purposes of Part VII, will be applicable subject to the provisions of the 'special arrangement'.

The replacement section 8 states that a provision of the MRCA PBS will be applicable subject to the 'special arrangement'. The application of the 'special arrangement' to the MRCA PBS being subject to the modifications made by section 16AAA.

The application of the 'special arrangement' is further modified by subsection 16AAA(9) which replaces for the purposes of the MRCA PBS, subsection 9(1) of the National Health Act instrument.

The replacement subsection 9(1) provides that the provisions of Division 2 of Part 2 of the National Health Act apply for the purposes supply of a pharmaceutical benefit by an approved supplier based on a paper-based prescription (excluding a medication chart prescription) written as the result of a telehealth attendance or phone attendance provided on or after 20 March 2020 to which an item in a Fee Schedule is applicable.

The reference to an item in a Fee Schedule (as incorporated into the Treatment Principles) will ensure that not only will prescriptions written by a General Practitioner or a specialist under a telehealth consultation be covered but also prescriptions issued by other health providers under similar arrangements.

The application of the 'special arrangement' is further modified by subsection 16AAA(10) which omits, for the purposes of the MRCA PBS, subsection 9(4) of the National Health Act instrument which had defined an 'item' for the purposes of the section.

The application of the 'special arrangement' is further modified by subsection 16AAA(11) which replaces for the purposes of the MRCA PBS, subsection 10(4) of the National Health Act instrument.

Subsection 10(4) of the National Health Act instrument refers to the supply of an 'authority prescription' under the 'special arrangement'.

As inserted by subsection 16AAA (11) the replacement subsection 10(4) provides that a prescription that would be an 'authority prescription' may be supplied under the 'special arrangement' set out in subsection 16AAA(1) if 'prior approval' has been obtained.

Attachment B to the Explanatory Statement provides details of the effect of the modifications to and the application to the RPBS and the MRCA PBS of the 'Special Arrangement' made under Section 100 of the *National Health Act 1953*.

Repatriation Pharmaceutical Benefits Scheme

Item 4 inserts a definition of 'special arrangement' into section 3 of the RPBS defining it as the instrument made by the Minister for Health under section 100 of the *National Health Act 1953*, the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the National Health Act instrument) which modifies the arrangements for the supply of pharmaceutical benefits under Part VII of the *National Health Act 1953*.

Item 5 makes a consequential amendment to section 16 of the RPBS to include a reference to new section 16AAA (inserted by item 3) which provides for the provision of pharmaceutical benefits under a 'special arrangement'.

Section 16 provides for the procedures to be followed by a community pharmacist in the ordinary supply of pharmaceutical benefits. The inclusion of the reference to section 16AAA provides with section 16A (continued dispensing) for exceptions to the ordinary supply.

Item 6 inserts new section 16AAA into the RPBS. Section 16AAA provides for the conditions that must apply for the supply of pharmaceutical benefits under the RPBS by a community pharmacist in the circumstances where the 'special arrangement' as defined in section 3 is in place.

The conditions as set out in subsection 16AAA(1) are:

- the supply must be made in accordance with the conditions specified in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the National Health Act instrument) as if the supply under the RPBS is a supply covered by that instrument; and
- the National Health Act instrument has effect as modified by the provisions set out in new section 16AAA to the extent that those conditions are applicable to the supply; and
- the supply occurs before the repeal of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*; and
- the supply otherwise conforms with the requirements of section 16AAA.

New subsection 16AAA(2) includes a Table which modifies certain references in the National Health Act instrument by replacing them with terms used in the RPBS for the purposes of supplying pharmaceutical benefits under new subsection 16AAA(1).

New subsection 16AAA(3) provides that for the purposes of the RPBS the definition of 'approved hospital authority' in the National Health Act instrument is omitted.

New subsection 16AAA(4) provides that for the purposes of the RPBS, the definition of 'approved hospital authority dispenser' in the National Health Act instrument will mean the community pharmacist or approved medical practitioner who has or who has supervised the dispensing of a pharmaceutical benefit supplied by an Approved Hospital Authority.

New subsection 16AAA(5) provides that for the purposes of the RPBS the definition of 'CTS claim' in the National Health Act instrument is omitted.

New subsection 16AAA(6) provides that for the purposes of the RPBS, the definition of 'medical chart prescription' in the National Health Act instrument will have the same meaning as it does in the RPBS.

New subsection 16AAA(7) provides that for the purposes of the RPBS, the definition of 'paper-based prescription' in the National Health Act instrument will have the same meaning as it does in the RPBS.

New subsection 16AAA(8) replaces for the purposes of the RPBS, section 8 of the National Health Act instrument.

Section 8 of the National Health Act instrument states that a provision of Part VII of the *National Health Act 1953*, or regulations and legislative instruments that are made for the purposes of Part VII, will be applicable subject to the provisions of the 'special arrangement'.

The replacement section 8 states that a provision of the RPBS will be applicable subject to the 'special arrangement'. The application of the 'special arrangement' to the RPBS being subject to the modifications made by section 16AAA.

The application of the 'special arrangement' is further modified by subsection 16AAA(9) which replaces for the purposes of the RPBS, subsection 9(1) of the National Health Act instrument.

The replacement subsection 9(1) provides that the provisions of Division 2 of Part 2 of the National Health Act apply for the purposes supply of a pharmaceutical benefit by an approved supplier based on a paper-based prescription (excluding a medication chart prescription) written as the result of a telehealth attendance or phone attendance provided on or after 20 March 2020 to which an item in a Fee Schedule is applicable.

The reference to an item in a Fee Schedule (as incorporated into the Treatment Principles) will ensure that not only will prescriptions written by a General Practitioner or a specialist under a telehealth consultation be covered but also prescriptions issued by other health providers under similar arrangements.

The application of the 'special arrangement' is further modified by subsection 16AAA(10) which omits, for the purposes of the RPBS, subsection 9(4) of the National Health Act instrument which had defined an 'item' for the purposes of the section.

The application of the 'special arrangement' is further modified by subsection 16AAA(11) which replaces for the purposes of the RPBS, subsection 10(4) of the National Health Act instrument.

Subsection 10(4) of the National Health Act instrument refers to the supply of an 'authority prescription' under the 'special arrangement'.

As inserted by subsection 16AAA (11) the replacement subsection 10(4) provides that a prescription that would be an 'authority prescription' may be supplied under the 'special arrangement' set out in subsection 16AAA(1) if 'prior approval' has been obtained.

<u>Attachment B</u> to the Explanatory Statement provides details of the effect of the modifications to and the application to the RPBS and the MRCA PBS of the 'Special Arrangement' made under Section 100 of the *National Health Act 1953*.

ATTACHMENT B

Modified Application of the 'Special Arrangement' Made Under Section 100 of the *National Health Act 1953* for the purposes of the MRCA PBS and the RPBS

Part 1—Preliminary

Sections 1 to 3 apply only for the purposes of the National Health Act instrument.

Section 4 provides for the instrument to be repealed "at the start of 30 September 2020". The repeal date may be extended or brought forward but the effect of subparagraph 16AAA(1)(a)(iv) is to accommodate such a change for the purposes of the Schemes.

Section 5 provides an outline of the measure being implemented by the National Health Act instrument and refers to the 'special arrangement' being put in place for a more convenient and effective supply pharmaceutical benefits to patients at risk of COVID-19.

Subsection 6(1) defines the terms used in the National Health Act instrument. Those terms are modified for the purposes of the Schemes by subsections 16AAA(2), (3), (4), (5), (6) and (7) with the relevant definitions being:

Act means the National Health Act 1953.

approved hospital authority dispenser means the community pharmacist or approved medical practitioner who has or who has supervised the dispensing of a Pharmaceutical benefit supplied by an Approved Hospital Authority.

approved medical practitioner has the same meaning as in the RPBS or the MRCA PBS.

approved pharmacist has the same meaning as in the RPBS or the MRCA PBS.

approved supplier has the same meaning as in the RPBS or the MRCA PBS.

medication chart prescription has the same meaning as in RPBS or the MRCA PBS.

paper-based prescription has the same meaning as in RPBS or the MRCA PBS.

Pharmaceutical benefit has the same meaning as in RPBS or the MRCA PBS.

phone attendance has the same meaning as in section 6 of the Health Insurance (Section 3C General Medical Services - COVID-19 Telehealth and Telephone Attendances) Determination 2020.

Poisons Standard means the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*).

Regulations means the National Health (Pharmaceutical Benefits) Regulations 2017.

telehealth attendance has the same meaning as in section 6 of the *Health Insurance* (Section 3C General Medical Services - COVID-19 Telehealth and Telephone Attendances) Determination 2020.

Subsection 6(2) of the National Health Act instrument provides that references in the 'special arrangement' to the:

• National Health Act 1953:

- National Health (Pharmaceutical Benefits) Regulations 2017;
- Health Insurance (Section 3C General Medical Services COVID-19 Telehealth and Telephone Attendances) Determination 2020;
- Health Insurance Act 1973; or the
- Therapeutic Goods Act 1989.

are references to that legislation as in force from time to time.

Subsection 6(3) of the National Health Act instrument provides that references in the 'special arrangement' to a digital image of a prescription indicate that subsections 11A(1) and (1A) of the Schemes have been complied with.

Part 2—Special arrangements for supplies of pharmaceutical benefits

Division 1—Preliminary

Section 7 of the National Health Act instrument refers to the pharmaceutical benefits provided for under the 'special arrangement'.

Subsection 7(1) refers to Division 2 of Part 2 of the 'special arrangement' and provides that all pharmaceutical benefits will be available for supply under Schemes except for:

- those benefits referred to in Schedule 8 or in both Schedule 4 and Appendix D to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*); and
- which may not be supplied on the basis of a digital image of a prescription or a copy of a prescription under the relevant State or Territory law where the pharmaceutical benefit would be supplied.

Subsection 7(2) of the National Health Act instrument refers to Division 3 of Part 2 of the 'special arrangement' and states that it will be applicable to all pharmaceutical benefits available for supply under the Schemes.

Section 8 of the National Health Act instrument (as modified by subsection 16AAA(8)) specifies that the provisions of the RPBS or the MRCA PBS apply subject to the provisions of the 'special arrangement'.

Section 9 of the National Health Act instrument (as modified by subsections 16AAA(2) and (9)) refers to the supplies of pharmaceutical benefits to which the 'special arrangement' applies.

Subsection 9(1) provides that Division 2 of Part 2 of the 'special arrangement' (Requirements for supply of pharmaceutical benefit - paper-based prescriptions) applies to the supply of a pharmaceutical benefit based on a paper-based prescription (excluding medication chart prescription) written as a result of a telehealth or phone attendance prior to the commencement of the Special Arrangement but after the provision for the new telehealth arrangements, providing the prescription is for an eligible item under a Fee Schedule (incorporated as in force from time to time for the purposes of the Treatment Principles).

Subsections 9(2)(a) and (b) provide that Division 2 of Part 2 of the 'special arrangement' does not apply to the supply of a pharmaceutical benefit if the

prescription must be in writing under the relevant State or Territory law in the area where the supply would be made.

Subsection 9(3) refers to Division 3 of Part 2 of the 'special arrangement' (*Requirements for receipt of a pharmaceutical benefit - all prescriptions*) and provides that the 'special arrangement' applies to the supply of a pharmaceutical benefit made by a community pharmacist or approved medical practitioner, meaning the provision requiring the patient or the pharmacist to acknowledge the receipt of the pharmaceutical benefit has been removed.

Division 2 – Requirements for supply of pharmaceutical benefit - paper-based prescriptions

Section 10 of the National Health Act instrument (as further modified by section 16AAA) modifies the application of section 16 of the Schemes to supplies of pharmaceutical benefits based on supplies to which Division 2 of Part 2 of the 'special arrangement' applies.

Subsection 10(2) provides that a community pharmacist or an approved medical practitioner may supply a pharmaceutical benefit to a person on the first presentation of a prescription if the prescriber has given the community pharmacist or medical practitioner a digital image of the prescription or a copy of the prescription, noting that a paper-based prescription includes both the pharmacist/patient copy and the Medicare/DVA copy of the prescription.

Subsection 10(3) provides that an approved hospital authority may supply a pharmaceutical benefit to a person on the first presentation of a prescription if the prescriber has given the approved hospital authority dispenser a digital image of the prescription or a copy of the prescription.

Subsection 10(4) (as modified by subsection 16AAA(11)) provides that if the prescription is or would be an authority prescription, the supplier may supply the pharmaceutical benefit under subsection 10(1) only if 'prior approval' has been obtained.

The 'prior approval' arrangements are those that are applied by the Veterans' Affairs Pharmaceutical Approvals Centre (VAPAC).

Section 11 of the National Health Act instrument (as modified by section 16AAA) provides for the modified application of section 51 of the Regulations relating to repeated supplies of pharmaceutical benefits.

Subsection 11(1) provides that for the supply of a pharmaceutical benefit from a digital image or copy of a prescription, this section modifies section 51 of the Regulations relating to repeated supplies of a pharmaceutical benefit being provided to a patient sooner than 20 or 4 days after the last supply of that same or equivalent pharmaceutical benefit if the supplier of the benefit reasonably believes that the previous supply was destroyed, lost or stolen, or that the supply of the benefit is immediately necessary for the treatment of the person, which requires the approved supplier to write the words "immediate supply necessary" and sign the Medicare/DVA copy of the prescription.

Subsections 11(2)(a) and (b) provide that in the circumstances where the supplier reasonably believes that the previous supply of the pharmaceutical benefit was

destroyed, lost or stolen, or that the supply of the benefit is immediately necessary for the treatment of the person, the supplier meets the requirements of paragraph 51(4)(b) or 51(4)(c) of the Regulations if they write the words "immediate supply necessary" and sign the copy of the prescription, the digital image of the prescription or a print out of the digital image of the prescription.

Section 12 of the National Health Act instrument (as modified by section 16AAA) provides for the modified application of section 52 of the Regulations relating to repeat authorisations.

Subsection 12(1) states that this section modifies section 52 of the Regulations relating to requirements for repeat authorisations of a pharmaceutical benefit.

Subsections 12(2)(a) and (b) provide that this section applies if an approved supplier provides a person with a pharmaceutical benefit from a digital image of a prescription or a copy of a prescription that contains a direction to repeat the supply the benefit, or from a copy of a prescription or print out of a digital image to which is attached a deferred supply authorisation or repeat authorisation that contains a direction to supply the benefit more than once, if there are repeats remaining on the prescription at the time of supply.

Subsections 12(3)(a) and (b) provide that paragraph 52(3)(a)(iii) of the Regulations, requiring the approved supplier to attach the repeat authorisation to the pharmacist/patient copy of the paper-based prescription and give the repeat authorisation and pharmacist/patient copy to the person to whom the pharmaceutical benefit is supplied, is taken to be met if the approved supplier attaches the repeat authorisation to a print out of the digital image of the prescription or copy of the prescription and retains the repeat authorisation and print out of the digital image of the prescription or the copy of the prescription for subsequent supply rather than give it to the person.

Section 13 of the National Health Act instrument (as modified by section 16AAA) provides for the modified application of section 53 of the Regulations relating to deferred supply.

Subsections 13(1) and (2)(a) and (b) provide that this section modifies section 53 of the Regulations relating to the requirements for deferred supply authorisations of a pharmaceutical benefit, allowing an approved supplier to defer the supply of one or more pharmaceutical benefits on a digital image of a prescription or a copy of a prescription when supplying one or more pharmaceutical benefits on the digital image or copy of that prescription.

Subsections 13(3)(a), (b) and (c) provide that paragraph 53(3)(c) of the Regulations, requiring the approved supplier to mark on the pharmacist/patient copy and the Medicare/DVA copy of the prescription the words "original supply deferred" and attach the deferred supply authorisation to the pharmacist/patient copy and give the authorisation and pharmacist/patient copy to the person for whom the prescription is written, is taken to be met if the approved supplier writes the words "original supply deferred" on the copy of the prescription, digital image of the prescription or print out of the digital image of the prescription and attaches the deferred supply authorisation to a print out of the digital image of the prescription or the copy of the prescription

and retains the deferred supply authorisation and print out of the digital image of the prescription or copy of the prescription for supply at a later time.

Subsection 13(4) states that if the supplier is retaining the deferred supply authorisation attached to the print out of the digital image of the prescription, the print out of the digital image of the prescription must include the words "original supply deferred".

Section 14 of the National Health Act instrument (as modified by section 16AAA) refers to a supply made on the basis of a digital image of a prescription or a copy of a prescription for a pharmaceutical benefit given to the supplier by a prescriber, or supply made on the basis of a deferred supply authorisation or repeat supply authorisation prepared in relation to a pharmaceutical benefit included in a digital image of a prescription or copy of a paper-based prescription, an approved supplier must retain either the digital image, print out of the digital image, copy of the prescription, repeat authorisation or deferred supply authorisation under the circumstances referred to in the tables for a period of 2 years from the date of supply.

Paragraph (b) of items 1 and 2 of the table in section 14 is modified by subsection 16AAA(2) to replace the references to "a CTS claim is made for the supply" with references to "a claim under the *claims rules* is made for the supply".

The 'claims rules' are defined in subsection 3(1) of the Schemes as meaning "the rules, in force from time to time, made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*".

Section 15 of the National Health instrument (as modified by section 16AAA) provides that for a prescriber who has written a prescription and given an approved supplier the digital image of the prescription or copy of the prescription for supply, the prescriber must retain the prescription or a copy of the prescription for a period of at least 2 years from the date of prescription.

Division 3 – Requirements for receipt of a pharmaceutical benefit- all prescriptions

Section 16 of the National Health Act instrument (as modified by section 16AAA) is applicable for the purposes of section 57 of the *National Health (Pharmaceutical Benefits) Regulations 2017* to supplies of pharmaceutical benefits based on prescriptions to which Division 3 of Part 2 of the 'special arrangement' applies.

The section refers to the acknowledgment of receipt of the pharmaceutical benefit and provides that section 57 of the Regulations does not apply to the supply of a pharmaceutical benefit where it is not practicable for the approved supplier to obtain from the person receiving the pharmaceutical benefit written acknowledgement of the receipt of the pharmaceutical benefit.

Part 3—Application, savings and transitional provisions

This section is applicable on the basis that principal instrument, the *National Health* (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020 commenced on 26 March 2020 is being amended by the *National Health* (COVID-19 Supply of Pharmaceutical Benefits) Amendment (Expansion of Telehealth and Telephone Attendances) Special Arrangement 2020.

It provides that the provisions in the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* prior to its amendment continue to apply for the supply of a pharmaceutical benefit that was made on a digital image of a prescription or copy of a prescription after 26 March 2020 and before the commencement of the amendment.

Statement of Compatibility with Human Rights

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

Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020

The Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020 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 Legislative Instrument

The Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020 modifies for the purposes of the Repatriation Pharmaceutical Benefits Scheme and the MRCA Pharmaceutical Benefits Scheme (the Schemes) a special arrangement made under section 100 of the National Health Act 1953 to make the supply of pharmaceutical benefits more convenient and effective.

The instrument amends the Schemes to incorporate (with modifications) the special arrangement which modifies the arrangements for the supply of a pharmaceutical benefit on a paper prescription before the presentation of that prescription to the approved pharmacist or approved medical practitioner making the supply.

The instrument also incorporates the provision of the special arrangement which removes the need for a person in receipt of a pharmaceutical benefit to acknowledge the receipt of the pharmaceutical benefit upon supply.

Human rights implications

Broadly, the *MRCA Pharmaceutical Benefits Scheme* and the *Repatriation Pharmaceutical Benefits Scheme* (the Schemes) assist with providing subsidised access to medicines for veterans and their dependents. The Schemes engage Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as they provide a positive step towards attaining the highest standard of health for all Australians, and assist in 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 incorporation into the Schemes of the provisions of the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* is compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020 is made under section 286 of the Military Rehabilitation and Compensation Act 2004 and section 91 of the Veterans' Entitlements Act 1986.

Conclusion

The Veterans' Affairs Pharmaceutical Benefits Schemes Amendment (Special Arrangement—COVID-19 Supply of Pharmaceutical Benefits) Determination 2020 is compatible with human rights as the amendments do not raise any human rights issues or impinge on any applicable rights or freedoms.

Mark Cormack

Deputy Secretary – Policy & Programs

Department of Veterans' Affairs