

REPLACEMENT EXPLANATORY STATEMENT

Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019 (Instrument 2019 No. R44/MRCC44)

EMPOWERING PROVISIONS

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

PURPOSE

The attached instrument (Instrument 2019 No. R44/MRCC44) varies, respectively:

- the *Repatriation Pharmaceutical Benefits Scheme* under the VEA (RPBS); and the
- the *MRCA Pharmaceutical Benefits Scheme* under the MRCA (MPBS);

(referred to as “the Schemes”).

The Schemes are legislative instruments that 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 at a concessional rate.

The Schemes include all items available to the general community under the Schedule of Pharmaceutical Benefits (the PBS) as well as the separate listings under the “Repatriation Schedule of Pharmaceutical Benefits” (RSPB) section of the PBS that are exclusive to clients of the Department of Veterans' Affairs (DVA) at a concessional rate.

The PBS (including the RSPB component) is established by a legislative instrument made under section 85 of the *National Health Act 1953* (National Health Act) and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The National Health Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits. The Department of Health administers the PBS under the National Health Act.

In the 2018-19 Budget, the Government announced the implementation of electronic prescribing from late 2019. This initiative included the implementation of active ingredient prescribing to increase patient understanding of the medicines they are taking and promote the uptake of generic and biosimilar medicines, supporting a viable long term market for these medicines in Australia.

Electronic Prescriptions

The *Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019* (instrument) strengthens the Schemes by making adjustments to support the regulation of electronic prescriptions and specifically provide assurance for privacy and security.

Similar amendments were made earlier this year to the PBS by the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019* which amended the *National Health (Pharmaceutical Benefits) Regulations 2017* (NHA Regulations). The National Health Act Regulations prescribe matters and set out details in relation to the operation of the PBS, including electronic prescriptions.

All existing prescription requirements provided in the Schemes (sections 11A and 11B) must be met when writing an electronic prescription or electronic medication chart prescription. The instrument requires the following additional information for electronic versions:

- Conformance ID of prescribing software.
- Unique electronic PBS prescription number.
- Valid RPBS prescriber Healthcare Provider Identifier – Individual (HPI-I), if available.
- Valid RPBS prescriber Healthcare Provider Identifier – Organisation (HPI-O).

RPBS prescribers include approved medical practitioners, dentists, optometrists, midwives and nurse practitioners.

The instrument includes requirements for the electronic prescription message to contain conformance identification numbers (Conformance IDs) provided to the Australian Digital Health Agency (the Agency) by the vendor of the clinical software used for the creation of an electronic prescription. This is in accordance with the technical conformance framework developed by the Agency.

The inclusion of a valid RPBS prescriber HPI-O and a valid RPBS prescriber HPI-I (if available), identifies the medical practice where the RPBS prescriber prepared the electronic prescription and the approved RPBS prescriber who prepared the electronic prescription.

To help improve patient safety and quality use of medicines, the instrument also includes that a patient's date of birth and the reason for the prescription may be included in the electronic prescription.

The implementation of electronic prescribing also enables the use of electronic prescribing from RPBS medication charts in the hospital and residential aged care settings. The optional inclusion of these items is reflected in the amendments to the Schemes, with this information only required to be provided in the claim if it is included in the electronic prescription.

Security and privacy of this information will be ensured through encryption of the electronic prescription that is only made available to authorised healthcare professionals, in alignment with the conformance framework. Furthermore, once the Department of Human Services receives the claims information, it will be protected by the secrecy provisions in section 135A of the National Health Act that require a person who receives personal information that is acquired in the performance of their duties under the Act not to divulge, or communicate that information to any person.

Section 25 of the Schemes provides that claims by pharmacists for payments for the supply of pharmaceutical benefits are made subject to section 24 of the Schemes and the "claims rules". The "claims rules" are defined in section 3 of the Schemes as the

“rules, in force from time to time, made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*.”

Section 40A as set out in Part 5B of the Schemes also has the effect of modifying the provisions of section 98AC of the National Health Act to apply to the collection of information concerning the supply of pharmaceutical benefits under the Schemes. As a consequence, section 135A will then be applicable to any information that is collected under the Schemes.

Active Ingredient Prescribing

The *Veterans’ Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019* strengthens the Schemes by making amendments to require the inclusion of active ingredients on RPBS prescriptions (including medications chart prescriptions) with some exceptions. Similar amendments to PBS prescriptions are being made by the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019* which will amend the National Health Act Regulations which prescribe matters and set out details in relation to the operation of the PBS, including active ingredient prescribing.

The instrument:

- requires the inclusion of active ingredients on all RPBS prescriptions (excluding handwritten prescriptions, paper-based medication charts in the residential aged care setting, prescriptions for medicines with four or more active ingredients, items as determined by the Secretary of the Department for Health for practicality and safety reasons, and pharmaceutical items which typically do not include active ingredients that appear only in the “Repatriation Pharmaceutical Benefits Scheme” section under the heading ‘Various’. Such items includes bandages and dressings;
- enables the inclusion of a brand on a prescription if deemed clinically necessary by the prescriber. This includes situations where the medication prescribed may pose a potential patient safety risk if the brand is not specified or to ensure medication continuance where a patient is familiar with a particular brand of their regular medicine;
- requires active ingredients to appear first, where a prescriber makes a clinical decision to include a brand name on a prescription; and
- prohibits prescribing software from automatically including brand names on prescriptions by default, to ensure doctors make a clinical decision regarding the inclusion of brand.

These amendments will not interfere with patients’ choice of medicines, or prescribers’ ability to prescribe the medicine that best meets their patient’s clinical need.

To support prescribers’ clinical decision regarding the inclusion of a brand, the Department of Health has engaged the Australian Commission on Safety and Quality in Healthcare (ACSQHC) to develop support documentation for prescribers, including Australian Guidelines for Active Ingredient Prescribing and a list of medicines where the inclusion of brand is recommended for patient safety. This support documentation will apply to the Schemes.

The instrument takes effect from 31 October 2019. However, a 12 month transition period would be provided to ensure prescribers have sufficient time to update prescribing software to versions which meet the new active ingredient prescribing requirements.

Active Ingredient Prescribing is part of a wider government strategy to ensure consistent and standardised medicines information. Presentation of the active ingredient name in all places where the consumer accesses medicines information is central to medication safety and this broader government strategy.

The instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

The instrument commences on 31 October 2019.

CONSULTATION

DVA has worked closely with the Department of Health in developing the instrument. The variations made by the instrument to the Schemes mirror the changes initiated by that Department to the National Health Act Regulations.

The Department of Health advised that they had engaged in broad consultation with peak clinical and industry bodies (including the Pharmacy Guild of Australia, Pharmaceutical Society of Australia, the Medical Software Industry Association and the Royal Australian College of General Practitioners) regarding the implementation of electronic prescribing and active ingredient prescribing and received widespread support.

In regard to the electronic prescribing measure, the Department worked extensively with the Australian Digital Health Agency and Services Australia (formerly DHS) to progress the legislative, technical and operational elements required to implement the measure. The Department of Health and the Australian Digital Health Agency worked together to ensure the alignment of the technical and legislative frameworks to reinforce an adherence to privacy and security principles.

The Australian Digital Health Agency has developed the electronic prescribing technical framework through a co-design approach with industry, including clinicians, consumer groups, clinical software vendors and the pharmaceutical industry.

The Department of Health has also led an ongoing engagement with state and territory governments through the Electronic Prescribing Working Group (EPWG) to align regulation of prescribing processes across Australia. Consultation took place with the various stakeholders through the release of an exposure draft of the amendments to the National Health Act Regulations with the feedback being positive with only minor changes being required.

While no external consultations took place between DVA and any of the interested parties the internal consultation process was quite extensive as the amendments to the National Health Act Regulations required some adaptation for the purpose of adopting the measures for the purposes of the Schemes.

RETROSPECTIVITY

None.

DOCUMENTS INCORPORATED BY REFERENCE

No.

HUMAN RIGHTS STATEMENT

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

The *Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019* 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

Electronic Prescriptions

The Repatriation Pharmaceutical Benefits Scheme and the MRCA Pharmaceutical Benefits Scheme (the Schemes) provide veterans and other eligible persons with access to all the pharmaceutical items available to the general community under the Pharmaceutical Benefits Scheme (PBS), and also an additional list contained in the Repatriation Schedule of Pharmaceutical Benefits (RSPB) which is available only to veterans and other eligible persons. The PBS (which includes the RSPB as a separate component) is made under section 85 of the *National Health Act 1953*.

The primary purpose of Part 1 of Schedule 1 and Part 1 of Schedule 2 of the instrument is to amend the Repatriation Pharmaceutical Benefits Scheme and the MRCA Pharmaceutical Benefits Scheme to strengthen those provisions that already allow for electronic prescribing. The instrument makes adjustments to support the regulation of electronic prescriptions and specifically provide assurance for privacy and security.

In addition to the existing prescription requirements set out in the Schemes (sections 11A and 11B), the instrument requires the following additional information for electronic versions:

- Conformance ID of prescribing software.
- Unique electronic RPBS prescription number.
- Valid RPBS prescriber Healthcare Provider Identifier – Individual (HPI-I), if available.
- Valid RPBS prescriber Healthcare Provider Identifier – Organisation (HPI-O).

To help improve patient safety and quality use of medicines the instrument also includes that a patient's date of birth and the reason for the prescription may be included in the electronic prescription.

The security and privacy of the information that is provided will be ensured through encryption of the electronic prescription that is only made available to authorised healthcare professionals, in alignment with the conformance framework.

In addition, once the Department of Human Services (Services Australia from 1 February 2020) receives the claims information, it will be protected by the secrecy provisions in section 135A of the *National Health Act 1953* that require a person who receives personal information that is acquired in the performance of their duties under the Act not to divulge, or communicate that information to any person.

Section 25 of the Schemes provides that claims by pharmacists for payments for the supply of pharmaceutical benefits are made subject to section 24 of the Schemes and the “claims rules”. The “claims rules” are defined in section 3 of the Schemes as the “rules, in force from time to time, made under subsections 98AC(4) and 99AAA(8) of the *National Health Act 1953*.”

The rules made under those provisions of the *National Health Act 1953*, the *National Health (Claims and under co-payment data) Rules 2012* have been amended to be applicable to the additional personal information being provided by electronic prescriptions.

Section 40A as set out in Part 5B of the Schemes also has the effect of modifying the provisions of section 98AC of the *National Health Act 1953* to apply to the collection of information concerning the supply of pharmaceutical benefits under the Schemes. As a consequence, section 135A will then be applicable to any information that is collected under the Schemes.

Active Ingredient Prescribing

The primary purpose of Part 2 of Schedule 1 and Part 2 of Schedule 2 of the instrument is to amend the Schemes to strengthen the requirements for active ingredient prescribing under the Schemes.

As a general rule active ingredients must be included on all RPBS prescriptions (excluding handwritten prescriptions, paper-based medication charts in the residential aged care setting, prescriptions for medicines with four or more active ingredients, other items as determined by the Secretary of the Department for Health for practicality and safety reasons, and other pharmaceutical items which typically do not include active ingredients that appear only in the “Repatriation Pharmaceutical Benefits Scheme” section under the heading ‘Various’. Such items includes bandages and dressings.

These amendments will not interfere with patients’ choice of medicines, or prescribers’ ability to prescribe the medicine that best meets their patient’s clinical need. Active Ingredient Prescribing is part of a wider government strategy to ensure consistent and standardised medicines information. Presentation of the active ingredient name in all places where the consumer accesses medicines information is central to medication safety and this broader government strategy.

Human rights implications

Broadly, the Schemes provide subsidised access to medicines for veterans and their eligible dependents. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for veterans and their families, and it assists 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 Schemes are compatible with Articles 2 and 12 of the ICESCR.

The instrument strengthens the provisions of the Schemes that already allow for electronic prescribing and strengthen the legislative assurance for privacy and security in relation to electronic prescriptions. Further, the instrument makes amendments to the Schemes to require the inclusion of active ingredients on RPBS prescriptions (including medications chart prescriptions) with some exceptions.

Conclusion

The instrument is compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms.

FURTHER EXPLANATION OF PROVISIONS

See: [Attachment A](#)

Darren Chester
Minister for Veterans and Defence Personnel
Rule-Maker

FURTHER EXPLANATION OF PROVISIONS

Section 1 – Name

This section provides that the title of the instrument is the *Veterans' Affairs Pharmaceutical Benefits Schemes (Electronic Prescriptions and Active Ingredient Prescribing) Amendment Instrument 2019*.

Section 2 – Commencement

This section provides that the instrument commences on 31 October 2019.

Section 3 – Authority

This section provides that the instrument is made under the *Veterans' Entitlements Act 1986* and the *Military Rehabilitation and Compensation Act 2004*.

Section 4 – Schedule(s)

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-Variations to the *Repatriation Pharmaceutical Benefits Scheme (Instrument 2013 No. R34)*

Part 1 - Amendments relating to electronic prescriptions

Items [1], [2], [3] and [4] - Section 3

Items 1 to 4 remove the definition of *approved electronic communication* and introduce the definition of *eligible electronic communication*. The instrument introduces a concept of eligible electronic communication in order to ensure that there is a broad concept of electronic communication consistent with the *Electronic Transactions Act 1999* that does not limit the types of electronic communications that can be used but provides the Secretary of the Department of Health the ability to specify particular types of electronic communications if required.

Item 4 also inserts the definitions *healthcare identifier* and *healthcare provider organisation*.

These definitions have been introduced as the *healthcare identifier* and the *healthcare provider organisation* are new data elements required in an electronic prescription and were not previously defined in the Schemes. See **Item 11** – additional requirements for electronic prescribing.

Item [5] – Paragraphs 11AA(a) and (b)

Item 5 repeals and substitutes paragraphs 11AA(a) and (b) so that a prescription for the supply of a pharmaceutical benefit is written in accordance with section 11A (prescriptions other than medication chart prescriptions) or section 11B (medication chart prescriptions), and if the prescription is an electronic prescription additionally in accordance with the requirements set out in section 11C (inserted below by **item 11**).

Item [6] – Paragraph 11A(1)(f)

Item 6 amends paragraph 11A(1)(f), to replace "to be supplied" with "prescribed". This will ensure consistent terminology in the context of an RPBS prescriber writing a prescription.

Item [7] – Subparagraph 11B(1)(b)(ii)

Item 7 inserts the words “other than an authority prescription referred to in subsection (4A)” after “authority prescription”, see **item 9** below for details of this new subsection 11B(4A).

Item [8] – Paragraphs 11B(4)(a) and (b)

Item 8 repeals and substitutes paragraphs 11B(4)(a) and (b) to align the wording of authority requirements for streamlined, telephone and written authorities prescribed using medication charts with the current wording for general PBS authority requirements.

Item [9] – After subsection 11B(4)

Item 9 creates a new subsection 11B(4A) to align authority prescription requirements for medication charts with the general PBS authority requirements. This section specifies the inclusion of authority approval numbers in some circumstances to be eligible for the payment of a special patient contribution by the Commonwealth.

Item [10] – At the end of section 11B

Item 10 inserts new subsection 11B(8) which defines “electronic medication charts” to ensure an electronic medication chart is in an approved form (as determined by the Secretary of the Department of Health under subsection 41(5) of the NHA Regulations) for the purpose of writing an electronic prescription.

Item [11] – After section 11B

Item 11 inserts new sections 11C and 11D after section 11B.

New section 11C details additional requirements for writing all electronic prescriptions. An RPBS prescriber must include in the metadata of the prescription the conformance identifier of the prescribing software, and a unique electronic prescription identifier generated by that software. The electronic prescription must include the Healthcare Provider Identifier - Individual (HPI-I) assigned to the RPBS prescriber (if available), and the Healthcare Provider Identifier - Organisation (HPI-O)

assigned to the healthcare provider organisation to which the RPBS prescriber is linked.

The inclusion of a valid RPBS prescriber HPI-I (if available) and RPBS prescriber HPI-O, identifies the approved RPBS prescriber who prepared the electronic prescription and the medical practice where the RPBS prescriber prepared the electronic prescription.

New section 11D provides that a patient's date of birth and the reason for prescribing the pharmaceutical benefit may be included as additional information when writing an electronic prescription.

Item [12] Subparagraph 45(2)(a)(ii)

Item 12 amends subparagraph 45(2)(a)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting "prescription, or copy of the electronic" after "electronic" (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [13] Subparagraph 45(2)(ab)(ii)

Item 13 amends subparagraph 45(2)(ab)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting "prescription, or copy of the electronic" after "electronic" (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [14] Subparagraph 45(2)(ac)(ii)

Item 14 amends subparagraph 45(2)(ac)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting "prescription, or copy of the electronic" after "electronic" (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [15] Subparagraph 45(2)(b)(ii)

Item 15 amends subparagraph 45(2)(b)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting "prescription, or copy of the electronic" after "electronic" (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Part 2 - Amendments relating to active ingredient prescribing

Item [1] Section 3

Item 1 inserts a definition for the term *pharmaceutical benefit has a drug* as having the same meaning as in Part VII of the *National Health Act 1953*.

Item [2] Paragraph 11A(1)(g)

Item 2 repeals and substitutes paragraph 11A(1)(g) which replaces the words “identifies in the prescription the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit” with the words “identifies in the prescription the *pharmaceutical benefit* in accordance with subsection (1A)”. See **item 3** below for details of this new subsection 11(1A).

Item [3] After subsection 11A(1)

Item 3 provides for the creation of subsection 11A(1A), which mandates the inclusion of active ingredients on RPBS prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 11A(1A)(a) provides that:

- handwritten prescriptions;
- prescriptions for medicines with four or more active ingredients;
- items as specified by the Secretary of the Department of Health; and
- prescriptions for the supply of a pharmaceutical benefit listed under the heading “Various” in the RPBS Schedule;

must identify the pharmaceutical benefit by such particulars as are necessary. This provision preserves the current requirements for these types of prescriptions and does not mandate the inclusion of active ingredients.

Subparagraph 11A(1A)(a)(iii) refers to a determination by the Secretary of the Department of Health under subparagraph 40(2A)(a)(iii) of the NHA Regulations that other pharmaceutical items are exempt from the active ingredient prescribing requirements as required.

The inclusion of subparagraph 11A(1A)(a)(iv) is to provide for an exemption for those other items that appear only in the RPBS Schedule under the heading ‘Various’. Under the RPBS a number of additional items which may only be prescribed under the RPBS have been listed. The listing includes a large number of items under the ‘Various’ heading which are not medicines and should not be subject to the requirements of the ‘Active Ingredient Prescribing’ provisions. Examples include “dressings” and “bandages”.

However, subparagraph 11A(1A)(b)(i) requires all other prescriptions for pharmaceutical benefits to identify the active ingredients for each pharmaceutical item prescribed.

Subparagraph 11A(1A)(b)(ii) allows for the specification of a brand name of a pharmaceutical benefit in addition to the active ingredient if it is necessary for the medical treatment of the patient.

Subsection 11A(1B) requires that active ingredients appear on PBS/ RPBS prescriptions before the brand name if the prescriber has elected to include a brand name on the prescription.

Subsection 11A(1C) ensures that these requirements do not apply where it would contravene State or Territory legislation.

Item [4] Subsection 11A(3)

Item 4 repeals and substitutes subsection 11A(3) to expand the situations where prescribing software cannot generate prescriptions with a default setting.

Paragraph 11A(3)(a) maintains the current prohibition that computer programs must not disallow the substitution of different brands of the same pharmaceutical item by default. That is, a computer program is required to indicate that brand substitution is permitted by default.

A further prohibition is added through paragraph 11A(3)(b) that disallows prescribing software to include specific brand names on prescriptions by default.

Item [5] Subparagraph 11B(3)(a)(i)

Item 5 repeals and substitutes subparagraph 11B(3)(a)(i) that relates to medication chart prescriptions which replaces the words “particulars sufficient to identify the pharmaceutical benefit” with the words “particulars to identify the pharmaceutical benefit in accordance with subsection (3A)”. See **item 7** below for details of new subsection 11B(3A).

Item [6] After paragraph 11B(3)(e)

Item 6 inserts new paragraph 11B(3)(ea) to expand the situations where prescribing software cannot generate prescriptions with a default function for medication charts.

New paragraph 11B(3)(ea) prohibits prescribing software to include specific brand names on medication chart prescriptions by default. This restriction only applies to medications chart prescriptions that meet the requirements of the new subsection 11B(3A). See **item 7** below for details of this new subsection (3A).

Item [7] After subsection 11B(3)

Item 7 provides for the creation of new subsections 11B(3A), (3B) and (3C).

Subsection 11B(3A) mandates the inclusion of active ingredients on medication chart prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 11B(3A)(a) provides that:

- handwritten medication chart prescriptions;
- medication chart prescriptions for medicines with four or more active ingredients;
- paper based medication charts (not electronic medication charts) in the residential aged care setting;
- medication chart prescriptions for items as specified by the Secretary of the Department of Health; and

- medication chart prescriptions for the supply of a pharmaceutical benefit listed under the heading ‘Various’ in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS;

must identify the pharmaceutical benefit by such particulars as are sufficient. This provision preserves the current requirements for these types of medication chart prescriptions and does not mandate the inclusion of active ingredients.

Subsection 11B(3A)(a)(iv) refers to a determination made by the Secretary of the Department of Health under subparagraph 40(2A)(a)(iii) of the NHA Regulations that other pharmaceutical items are exempt from the active ingredient prescribing requirements for medication charts as required.

The inclusion of subparagraph 11B(3A)(a)(v) is to provide for an exemption for those other items that appear only in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS under the heading ‘Various’. The items listed under the ‘Various’ heading are not medicines and should not be subject to the requirements of the ‘Active Ingredient Prescribing’ provisions. Such items include “dressings” and “bandages”.

However, subparagraph 11B(3A)(b)(i) requires all other medication chart prescriptions to identify the active ingredients for each pharmaceutical item prescribed.

Subparagraph 11B(3A)(b)(ii) allows for the specification of a brand name of a pharmaceutical benefit in addition to the active ingredient if it is necessary for the medical treatment of the patient.

Subsection 11B(3B) requires the active ingredients appear on RPBS prescriptions before the brand name if the prescriber has elected to include a brand name.

Subsection 11B(3C) outlines that these requirements do not apply where it would contravene State or Territory legislation.

Item [8] At the end of Part 6

Item 8 inserts new section 47 into Part 6 of the RPBS that allows a 12 month transitional period for the active ingredient prescribing regulatory changes.

Subsection 47(1) makes the new regulatory requirements mandatory from 1 November 2020.

Subsections 47(2) and (3) allows for prescriptions and medication chart prescriptions written between 31 October 2019 and 1 November 2020 to be valid prescriptions under sections 11A and 11B even if they do not meet the new regulatory requirements.

Schedule 2-Variations to the *MRCIA Pharmaceutical Benefits Scheme* (Instrument 2013 No. MRCC 34)

Part 1 - Amendments relating to electronic prescriptions

Item [1], [2], [3] and [4] - Section 3

Items 1 to 4 remove the definition of *approved electronic communication* and introduce the definition of *eligible electronic communication*. The instrument introduces a concept of eligible electronic communication in order to ensure that there is a broad concept of electronic communication consistent with the *Electronic Transactions Act 1999* that does not limit the types of electronic communications that can be used but provides the Secretary of the Department of Health the ability to specify particular types of electronic communications if required.

Item 4 also inserts the definitions *healthcare identifier* and *healthcare provider organisation*.

These definitions have been introduced as the *healthcare identifier* and the *healthcare provider organisation* are new data elements required in an electronic prescription and were not previously defined in the Schemes. See **item 11** – additional requirements for electronic prescribing.

Item [5] – Paragraphs 11AA(a) and (b)

Item 5 repeals and substitutes paragraphs 11AA(a) and (b) so that a prescription for the supply of a pharmaceutical benefit is written in accordance with section 11A (prescriptions other than medication chart prescriptions) or section 11B (medication chart prescriptions), and if the prescription is an electronic prescription additionally in accordance with the requirements set out in section 11C (inserted below by **item 11**).

Item [6] – Paragraph 11A(1)(f)

Item 6 amends paragraph 11A(1)(f), to replace "to be supplied" with "prescribed". This will ensure consistent terminology in the context of an MPBS prescriber writing a prescription

Item [7] – Subparagraph 11B(1)(b)(ii)

Item 7 inserts the words "other than an authority prescription referred to in subsection (4A)" after "authority prescription", see **item 9** below for details of this new subsection 11B(4A).

Item [8] – Paragraphs 11B(4)(a) and (b)

Item 8 repeals and substitutes paragraphs 11B(4)(a) and (b) to align the wording of authority requirements for streamlined, telephone and written authorities prescribed using medication charts with the current wording for general PBS authority requirements.

Item [9] – After subsection 11B(4)

Item 9 inserts new subsection 11B(4A) to align authority prescription requirements for medication charts with the general PBS authority requirements. This section specifies the inclusion of authority approval numbers in some circumstances to be eligible for the payment of a special patient contribution by the Commonwealth.

Item [10] – At the end of section 11B

Item 10 adds the definition of “electronic medication chart” in new subsection 11B(8) to ensure an electronic medication chart is in an approved form (as determined by the Secretary of the Department of Health under subsection 41(5) of the NHA Regulations) for the purpose of writing an electronic prescription.

Item [11] – After section 11B

Item 11 inserts new sections 11C and 11D after section 11B.

New section 11C details additional requirements for writing all electronic prescriptions. An MPBS prescriber must include in the metadata of the prescription the conformance identifier of the prescribing software, and a unique electronic prescription identifier generated by that software.

The electronic prescription must include the Healthcare Provider Identifier - Individual (HPI-I) assigned to the MPBS prescriber (if available), and the Healthcare Provider Identifier - Organisation (HPI-O) assigned to the healthcare provider organisation to which the MPBS prescriber is linked.

The inclusion of a valid MPBS prescriber HPI-I (if available) and MPBS prescriber HPI-O, identifies the approved MPBS prescriber who prepared the electronic prescription and the medical practice where the MPBS prescriber prepared the electronic prescription.

New section 11D provides that a patient’s date of birth and the reason for prescribing the pharmaceutical benefit may be included as additional information when writing an electronic prescription.

Item [12] Subparagraph 45(2)(a)(ii)

Item 12 amends subparagraph 45(2)(a)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting “prescription, or copy of the electronic” after “electronic” (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [13] Subparagraph 45(2)(ab)(ii)

Item 13 amends subparagraph 45(2)(ab)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting “prescription, or copy of the electronic” after “electronic” (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [14] Subparagraph 45(2)(ac)(ii)

Item 14 amends subparagraph 45(2)(ac)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting “prescription, or copy of the electronic” after “electronic” (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Item [15] Subparagraph 45(2)(b)(ii)

Item 15 amends subparagraph 45(2)(b)(ii) to include that an approved supplier must retain for at least 2 years after supply, either the electronic prescription or a copy of the electronic prescription by inserting “prescription, or copy of the electronic” after “electronic” (second occurring). This change aligns with document keeping requirements for paper-based prescriptions.

Part 2 - Amendments relating to active ingredient prescribing

Item [1] Section 3

Item 1 inserts a definition for the term *pharmaceutical benefit has a drug* as having the same meaning as in Part VII of the *National Health Act 1953*.

Item [2] Paragraph 11A(1)(g)

Item 2 repeals and substitutes paragraph 11A(1)(g) which replaces the words “identifies in the prescription the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit” with the words “identifies in the prescription the *pharmaceutical benefit* in accordance with subsection (1A)”. See **item 3** below for details of this new subsection (1A).

Item [3] Subsection 11A(1)

Item 3 provides for the creation of subsection 11A(1A), which mandates the inclusion of active ingredients on MPBS prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 11A(1A)(a) provides that:

- handwritten prescriptions;
- prescriptions for medicines with four or more active ingredients;
- items as specified by the Secretary of the Department of Health; and
- prescriptions for the supply of a pharmaceutical benefit listed under the heading ‘Various’ in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS;

must identify the pharmaceutical benefit by such particulars as are necessary. This provision preserves the current requirements for these types of prescriptions and does not mandate the inclusion of active ingredients.

Subparagraph 11A(1A)(a)(iii) refers to a determination by the Secretary of the Department of Health under subparagraph 40(2A)(a)(iii) of the NHA Regulations that

other pharmaceutical items are exempt from the active ingredient prescribing requirements as required.

The inclusion of subparagraph 11A(1A)(a)(iv) is to provide for an exemption for those other items that appear only in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS under the heading ‘Various’. The section includes a large number of items under the ‘Various’ heading which are not medicines and should not be subject to the requirements of the ‘Active Ingredient Prescribing’ provisions. Such items include “dressings” and “bandages”.

However, subparagraph 11A(1A)(b)(i) requires all other prescriptions for pharmaceutical benefits to identify the active ingredients for each pharmaceutical item prescribed.

Subparagraph 11A(1A)(b)(ii) allows for the specification of a brand name of a pharmaceutical benefit in addition to the active ingredient if it is necessary for the medical treatment of the patient.

Subsection 11A(1B) requires that active ingredients appear on MPBS prescriptions before the brand name if the prescriber has elected to include a brand name on the prescription.

Subsection 11A(1C) ensures that these requirements do not apply where it would contravene State or Territory legislation.

Item [4] Subsection 11A(3)

Item 4 repeals and substitutes subsection 11A(3) to expand the situations where prescribing software cannot generate prescriptions with a default setting.

Paragraph 11A(3)(a) maintains the current prohibition that computer programs must not disallow the substitution of different brands of the same pharmaceutical item by default. That is, a computer program is required to indicate that brand substitution is permitted by default.

A further prohibition is added through new paragraph 11A(3)(b) that disallows prescribing software to include specific brand names on prescriptions by default.

Item [5] Subparagraph 11B(3)(a)(i)

Item 5 repeals and substitutes subparagraph 11B(3)(a)(i) that relates to medication chart prescriptions which replaces the words “particulars sufficient to identify the pharmaceutical benefit” with the words “particulars to identify the pharmaceutical benefit in accordance with subsection (3A)”. See **item 7** below for details of this new subsection (3A).

Item [6] After paragraph 11B(3)(e)

Item 6 inserts new paragraph 11B(3)(ea) to expand the situations where prescribing software cannot generate prescriptions with a default function for medication charts. New paragraph 11B(3)(ea) prohibits prescribing software to include specific brand names on medication chart prescriptions by default. This restriction only applies to

medications chart prescriptions that meet the requirements of the new subsection 11B(3A). See **item 7** below for details of this new subsection 11B(3A).

Item [7] After subsection 11B(3)

Item 7 provides for the creation of a new subsections 11B(3A), (3B) and (3C).

Subsection 11B(3A) mandates the inclusion of active ingredients on medication chart prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 11B(3A)(a) provides that:

- handwritten medication chart prescriptions;
- medication chart prescriptions for medicines with four or more active ingredients;
- paper based medication charts (not electronic medication charts) in the residential aged care setting;
- medication chart prescriptions for items as specified by the Secretary of the Department of Health; and
- medication chart prescriptions for the supply of a pharmaceutical benefit listed under the heading ‘Various’ in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS;

must identify the pharmaceutical benefit by such particulars as are sufficient. This provision preserves the current requirements for these types of medication chart prescriptions and does not mandate the inclusion of active ingredients.

Subsection 11B(3A)(a)(iv) refers to the determination made by the Secretary of the Department of Health under subparagraph 40(2A)(a)(iii) of the NHA Regulations that other pharmaceutical items are exempt from the active ingredient prescribing requirements for medication charts as required.

Subparagraph 11B(3A)(a)(v) provides for an exemption for other pharmaceutical items that appear only in the “Repatriation Pharmaceutical Benefits Scheme” section of the PBS under the heading ‘Various’. Such items include “dressings” and “bandages”.

However, subparagraph 11B(3A)(b)(i) requires all other medication chart prescriptions to identify the active ingredients for each pharmaceutical item prescribed.

Subparagraph 11B(3A)(b)(ii) allows for the specification of a brand name of a pharmaceutical benefit in addition to the active ingredient if it is necessary for the medical treatment of the patient.

Subsection 11B(3B) requires the active ingredient to appear before the brand name where the MPBS prescriber has elected to include a brand name.

Subsection 11B(3C) outlines that these requirements do not apply where it would contravene State or Territory legislation.

Item [8] Part 6

Item 8 inserts new section 47 into Part 6 of the MPBS that allows a 12 month transitional period for the active ingredient prescribing regulatory changes.

Subsection 47(1) makes the new regulatory requirements mandatory from 1 November 2020.

Subsections 47(2) and (3) allows for prescriptions and medication chart prescriptions written between 31 October 2019 and 1 November 2020 to be valid prescriptions under sections 11A and 11B even if they do not meet the new regulatory requirements.