

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019

By authority of the Minister for Health

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (the Act) and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters that are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

Paragraph 89(a) of the Act relevantly provides that a person is not entitled to receive a pharmaceutical benefit supplied by an approved pharmacist unless the supply is made on presentation of a prescription written by a PBS prescriber in accordance with the Act and the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations). PBS prescribers include approved medical practitioners, dentists, optometrists, midwives and nurse practitioners.

Section 105 of the Act provides that the regulations may specify terms and conditions relating to the supply of pharmaceutical benefits and provides rules about writing prescriptions for the purposes of the PBS.

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 (AIP) 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.

In order to increase understanding of active ingredients and support for generic and biosimilar medicines, the government committed to ensure the identification of active ingredient names on prescriptions, without impeding the professional and clinical judgment of prescribers.

The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS. The primary purpose of the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019* (the Regulations) amends the Principal regulations to require the inclusion of active ingredients on PBS prescriptions (including medications chart prescriptions) with some exceptions.

The Regulations:

- require the inclusion of active ingredients on all PBS prescriptions (excluding handwritten prescriptions, paper-based medication charts in the residential aged care setting, prescriptions

for medicines with four or more active ingredients and other items as determined by the Secretary for practicality and safety reasons);

- enable 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;
- require active ingredients to appear first, where a prescriber makes a clinical decision to include a brand name on a prescriptions; and
- prohibit 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 do 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.

The Regulations take effect from 31 October 2019. However, a 12 month transition period is 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 implementation of active ingredient prescribing is also identified as a joint commitment in the Department of Health's 2017 Strategic Agreements with the Generic and Biosimilar Medicines Association and Medicines Australia.

The Department of Health engaged in extensive consultation with peak clinical and industry bodies regarding the implementation of active ingredient prescribing. The Department developed the active ingredient prescribing implementation strategy through a co-design approach with industry, including clinicians, consumer groups, clinical software vendors and the pharmaceutical industry. The Department consulted directly with Services Australia, the Department of Veterans' Affairs, the Therapeutic Goods Administration and the ACSQHC which are supportive of this initiative. The Department also consulted with state and territory governments, which are also supportive.

Details of the Regulations are set out in the [Attachment](#).

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

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

The Regulations commence on 31 October 2019.

Authority: Section 140 of the *National Health Act 1953*

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*

Section 1-Name

This section provides that the title of the instrument is the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019*.

Section 2 - Commencement

This section provides that the instrument will commence on 31 October 2019.

Section 3 - Authority

This section provides that the instrument is made under the *National Health Act 1953* (the Act).

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 - Amendments

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

Item [1] Section 5(1)

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 40(1)(d)

Item 2 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 (2A)". See item 3 below for details of this new subsection (2A).

Item [3] Subsection 40(2)

Item 3 creates a new subsection 40(2A), which mandates the inclusion of active ingredients on PBS prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 40(2A)(a) specifies that handwritten prescriptions, prescriptions for medicines with four or more active ingredients and items as determined by the Secretary 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. Subsection 40(2A)(a)(iii) provides for the Secretary of the Department of Health to determine other pharmaceutical items as exempt from the active ingredient prescribing requirements as required.

However, subparagraph 40(2A)(b)(i) requires all other prescriptions for pharmaceutical benefits to identify the active ingredients for each pharmaceutical item prescribed. Subparagraph 40(2A)(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 40(2B) requires that active ingredients must appear on PBS prescriptions before the brand name if the prescriber has elected to include a brand name on the prescription.

Subsection 40(2C) ensures that these requirements do not apply where it would contravene State or Territory legislation.

Item [4] Subsection 40(4)

Item 4 expands the situations where prescribing software cannot generate prescriptions with a default setting. Paragraph 40(4)(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 40(4)(b) that disallows prescribing software to include specific brand names on prescriptions by default.

Item [5] Subparagraph 41(2)(a)(i)

Item 5 relates to medication chart prescriptions and replaces the words "particulars sufficient to identify the pharmaceutical benefit" with the words "particulars to identify the pharmaceutical benefit in accordance with subsection (2A)". See item 7 below for details of this new subsection (2A).

Item [6] Paragraph 41(2)(e)

Item 6 expands the situations where prescribing software cannot generate prescriptions with a default function for medication charts. A further restriction is added through paragraph 41(2)(ea) which prohibits prescribing software to include specific brand names on medication chart prescriptions by default. This restriction only applies to medication chart prescriptions that meet the requirements of the new subsection 41(2A). See item 7 below for details of this new subsection (2A).

Item [7] subsection 41(2)

Item 7 creates a new subsection 41(2A), 41(2B) and 41(2C).

Subsection 41(2A) mandates the inclusion of active ingredients on medication chart prescriptions, and identifies those items that are exempt from this requirement.

Paragraph 41(2A)(a) requires that for 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 and medication chart prescriptions for items as specified by the Secretary 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 41(2A)(a)(iv) provides for the Secretary of the Department of Health to determine other pharmaceutical items as exempt from the active ingredient prescribing requirements for medication charts as required.

However, subparagraph 41(2A)(b)(i) requires all other medication chart prescriptions to identify the active ingredients for each pharmaceutical item prescribed. Subparagraph 41(2A)(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 41(2B) requires the active ingredient to appear before the brand name where the prescriber has elected to include a brand name.

Subsection 41(2C) outlines that these requirements do not apply where it would contravene State or Territory legislation.

Item [8] Part 9

Item 8 creates a new section 102 that allows a 12 month transitional period for the active ingredient prescribing regulatory changes. Subsection 102(1) makes the new regulatory requirements mandatory from 1 November 2020. Subsection 102(2) and (3) allows for prescriptions and medication chart prescriptions written between 31 October 2019 and 1 November 2020 to be valid prescriptions under section 40 and 41 even if they do not meet the new regulatory requirements.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations

The *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019* (the Regulations) are 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 Regulations amend the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Principal Regulations) to support amendments to the *National Health Act 1953* (the Act) made by the *National Health Amendment (Pharmaceutical Benefits - Budget and Other Measures) Act 2018*.

The Pharmaceutical Benefits Scheme (PBS) provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The PBS operates under Part VII of the Act which regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. The Principal Regulations prescribe matters and set out details in relation to the operation of the PBS.

The primary purpose of the *National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019* (the Regulations) is to require the inclusion of Active Ingredients on all eligible PBS prescriptions. The Regulations make adjustments to require PBS prescribers to include active ingredients on all PBS prescriptions, excluding handwritten prescriptions, paper-based medication charts in the residential aged care setting, prescriptions for medicines with four or more active ingredients and other items as determined by the Secretary for practicality and safety reasons. The regulatory amendments also require active ingredients to appear before brand where a prescriber determines that the inclusion of a brand name is necessary for the clinical treatment of their patient.

Human rights implications

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. 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 all Australians, 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 Principal Regulations are compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The regulations improve patient safety and medicines safety by requiring the inclusion of active ingredients on PBS prescriptions. Presentation of the active ingredient in all places where the consumer accesses medicines information is central to medication safety. It will also improve the long-term financial sustainability of the PBS as a viable medicines subsidy scheme.

Conclusion

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

The Hon. Greg Hunt MP, Minister for Health