

EXPLANATORY STATEMENT

National Health Act 1953

*National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists)
Instrument 2023*

PB 17 of 2023

Purpose and operation

The *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023* (the Amending Instrument) amends the *National Health (Pharmaceutical Benefits)(Conditions of approval for approved pharmacists) Determination 2017* (the Determination) to set out the conditions for which approved pharmacists must comply in supplying pharmaceutical benefits, in addition to the conditions specified in subsection 92A(1). The purpose of the Amending Instrument is to clarify the policy intent that an approved pharmacist should not be involved in the supply of pharmaceutical benefits at premises which are not approved, or make a claim for payment or a claim for an advance payment in respect of pharmaceutical benefits supplied at or from premises which are not the approved premises, unless the Secretary of the Department of Health and Aged Care (the Secretary) has granted permission to the pharmacist in respect of those other premises, following disaster or exceptional circumstances.

Consequential amendments are made to the following four instruments:

National Health (Chemotherapy Prescribing) Special Arrangement 2020

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017

Background

Section 90 of the *National Health Act 1953* (the Act) provides for the Secretary, or the Secretary's delegate, to approve a pharmacist to supply pharmaceutical benefits at particular premises to persons who are physically present at those premises at the time of supply.

An approved pharmacist may also supply pharmaceutical benefits from the approved premises (see subsection 90(5AA) of the Act) by delivery to a person who is not able to attend the premises (for example delivery to a person's home).

Where a pharmacist desires to supply pharmaceutical benefits at more than one premises, a separate application must be made in respect of each of the premises and where approval is granted in respect of two or more premises, a separate approval is granted in respect of each of those premises (see subsection 90(2) of the Act).

The Amending Instrument clarifies the intent that the only situation when supply of pharmaceutical benefits can occur at premises other than the approved premises is where the approved premises have been affected by disaster or exceptional circumstances and the

Secretary has granted permission to the approved pharmacist to supply pharmaceutical benefits at those other premises (see section 91A of the Act).

Authority

The Amending Instrument is made pursuant to subsections 92A(1A) and 100(2) of the Act.

Subsection 92A(1A) of the Act provides that the Minister may, by legislative instrument, determine conditions which apply to an approved pharmacist, or an approved medical practitioner under Part 5 of the Act.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1) of the Act. Subsection 100(1) provides that the Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to the following persons: those who are living in isolated areas; or, those who are receiving treatment in which pharmaceutical benefits (other than those to which subsection 100(1A) applies) are inadequate for that treatment; or, if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

This Amending Instrument commences on 1 June 2023.

Consultation

The Department of Health and Aged Care (the Department) has consulted on the proposed changes, through a limited exposure draft process, with the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Pharmacy Board of Australia and State/Territory pharmacy regulators. The outcome of this consultation was supportive of the change as it clarifies the policy intent that pharmaceutical benefits should only be supplied to persons at or from pharmacy premises which are approved.

Approved pharmacists will be advised of the changes prior to commencement. This will be conducted through letters sent to approved pharmacists and stakeholder organisations; pharmacy journal articles; and the Department's website.

General

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

Details of this Amending Instrument are set out in the **Attachment A**.

The Amending Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023*

Section 1 – Name

Section 1 provides that the name of the Amending Instrument is the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023*. This section also provides that the Amending Instrument may also be cited as PB 17 of 2023.

Section 2 – Commencement

Section 2 provides that the Amending Instrument commences on 1 June 2023.

Section 3 - Authority

Section 3 provides the Amending Instrument is made under subsections 92A(1A) and 100(2) of the *National Health Act 1953*.

Section 4 - Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Amending 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 — Main Amendments

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Item 1 – Before section 1

Item 1 inserts a new heading of ‘Part 1 – Preliminary’, in the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* (the Determination) before section 1.

Item 2 – Subsection 1(1)

Item 2 removes the reference to ‘of approval’ from the name of the Determination, so the new name of the Determination will be the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017*. This amendment clarifies that the conditions apply to approved pharmacists once approved, rather than a pre-requisite of approval.

Item 3 – Section 4 (note)

Item 2 repeals the note in section 4 of the Determination and replaces it with two new notes.

New Note 1 clarifies that any conduct of an approved pharmacist that contravenes the conditions specified in section 92A of the Act can result in the approved pharmacist being referred to the Pharmaceutical Services Committee of Inquiry, under section 114 or section 116 of the Act, which can lead to the suspension or revocation of the pharmacist’s approval to supply pharmaceutical benefits.

New Note 2 clarifies that the dispensing of drugs and medicinal preparations is also regulated under various State and Territory laws and the Determination does not override those laws. If an approved pharmacist contravenes a State or Territory dispensing requirement then that is a matter for the relevant State or Territory regulator.

Item 4 – Section 5 (after the heading)

Item 4 inserts two new notes.

New Note 1 clarifies that several expressions used in the Determination including ‘pharmacist’, ‘premises’, ‘prescription for the supply of a pharmaceutical benefit’, and ‘supply of pharmaceutical benefits at premises’ are to have the same meaning as defined in the Act.

New Note 2 clarifies that the expression ‘National Law’ has the same meaning as defined in the *Health Insurance Act 1973*.

Item 5 – Section 5

Item 5 defines common terms used in the Determination.

Most definitions under this item have the same meaning as defined under, or in relation to, the Act, the *National Health (Pharmaceutical Benefits) Regulations 2017* or the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, for example, ‘approval number’, ‘approved pharmacist’, ‘brand’, ‘continued dispensing prescription’, ‘deferred supply authorisation’, ‘electronic prescription’, ‘extemporaneously-prepared pharmaceutical benefit’, and ‘listed brand’.

This item also clarifies the reference to ‘Act’ to mean the *National Health Act 1953* and includes the definition of the common term of ‘arrangement’.

In addition to the above terms, this item defines ‘dispensing step’ as meaning each step involved in the dispensing of a pharmaceutical benefit which is listed and is intended to convey that each of these steps must be performed at the approved premises by, or under the direct supervision of, a pharmacist who is registered under the National Law in the profession of pharmacy. If any of these steps are performed by a person using remote access, or at premises which are not the approved premises, then these steps are not satisfied.

It provides that where a pharmaceutical benefit is to be supplied on the basis of a prescription (other than a medication chart prescription), repeat authorisation or deferred supply authorisation, it must be reviewed by, or under the direct supervision of, a registered pharmacist who is physically present at the approved premises when the prescription is being reviewed.

If the pharmaceutical benefit requires any form or preparation, for example an extemporaneously prepared benefit, the preparation must be done at the approved premises by, or under the direct supervision of, a registered pharmacist.

Direct supervision by a registered pharmacist is intended to convey that the registered pharmacist is physically present at the approved premises to oversee, provide constant direction, feedback and assistance to the person who is not themselves a registered pharmacist, but who too is physically present at the approved premises.

A label must be produced and attached to the packaging of the pharmaceutical benefit at the approved premises which includes the patient’s details, details of the pharmaceutical benefit, directions for use, the date the medication is dispensed and the full cost of the benefit.

The requirement to record the dispensing of the benefit in the pharmacy’s system is intended to convey that the person who is dispensing the benefit at the approved premises accesses the approved pharmacist’s dispensing system, generally a computer-based system, used to record the dispensing of pharmaceutical benefits; generate a label to affix to the packaging for the benefit; and to generate the repeat authorisation, at the approved premises.

Notes 1 and 2 at the end of the definition of ‘dispensing steps’ further clarifies the form of the prescription referenced in paragraph (a) and subparagraph (c)(ii), (iv) and (v) of the definition.

Note 3 explains that the form of a pharmaceutical benefit includes the strength, type of unit, size of unit or otherwise, to account for extemporaneously-prepared benefits as well as ready prepared benefits.

Item 6 – Section 5 (definition of *medication chart prescription*)

Item 6 omits the reference to ‘*National Health (Pharmaceutical Benefits) Regulations 2017*’ and replaces it with ‘Regulations’. This is a consequential amendment to the insertion of the new definition of ‘Regulations’ which means the *National Health (Pharmaceutical Benefits) Regulations 2017* (see item 9) and ensures consistency across the Determination when referring to the Regulations.

Items 7 – Section 5

Items 7 inserts new definitions which are referenced in the Determination, most of which have the same meaning as defined under the Act or the Regulations.

Item 8 – Section 5 (*definition of reference time*)

Item 8 removes the definition of ‘reference time’, which is a term no longer used in the Determination to reference Pharmaceutical Society of Australia publications.

Item 9 – Section 5

Item 9 inserts two new definitions. Firstly, a ‘registered pharmacist’ is defined as an individual registered under the National Law in the pharmacy profession. Secondly, ‘repeat authorisation’ is clarified to have the same meaning as in the Regulations. This item also clarifies that the reference to ‘Regulations’ means the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Item 10 – After section 5

Item 10 inserts a new section 5A, which sets out the application of the Determination to clearly articulate what supplies are captured.

Paragraphs 5A(a) and (b) provide that the conditions in the Determination apply to the supply, or purported supply, of a drug or medicinal preparation that is to be a supply of a pharmaceutical benefit under Part VII of the Act (other than a supply taken, because of subsections 99(2A), (2AB) or (2B) of the Act, to be a supply other than under Part VII of the Act).

Subsections 99(2A), (2AB) and (2B) of the Act provide that a supply of a pharmaceutical benefit is not taken to be a supply under Part VII of the Act, except for the purposes of Division 1A of Part VII (safety net and under co-payment data), where the Commonwealth price of a pharmaceutical benefit does not exceed the relevant patient co-payment for the type of patient. These supplies are colloquially referred to as ‘under patient co-payment supplies’ and are considered outside the operation of Part VII (other than for safety net), because the supplies do not require subsidy from the Commonwealth, and therefore there is no need to subject them to the requirements in Part VII.

The Minister’s power to make conditions in subsection 92A(1A) extends only to approved pharmacists for supply of pharmaceutical benefits under Part VII

The Notes under new section 5A set out situations where, despite the medication being listed as a pharmaceutical benefit, the supply is not made as a pharmaceutical benefit under Part VII of the Act. These supplies are colloquially referred to as a ‘private supply’. This can occur if the patient is not an Australian resident or if the patient does not meet the criteria for which the pharmaceutical benefit is listed. The Determination does not apply to the supply of a pharmaceutical benefit listed medication where it is supplied as a ‘private supply’.

Item 11 – Before section 6

Item 11 inserts the new heading of ‘Part 2 – Conditions’ before section 6.

Item 12 – Section 6

Item 12 omits the reference to ‘dispensing prescriptions for pharmaceutical benefits and in supplying’ and substitutes it with ‘dispensing and supplying’ to clarify that the standards of practice apply to the dispensing and supply of pharmaceutical benefits.

Items 13 and 14 – Paragraph 6(c) and 6(d)

Items 13 and 14 correct the title and date of the publications by the Pharmaceutical Society of Australia.

Item 15 – Section 6 (examples and notes)

Item 15 repeals the examples and notes under section 6 of the Determination and replaces it with two new notes.

New Note 1 provides examples of how a patient can ensure an approved pharmacist has ready access to the patient’s medication history, to reduce risks of patient harm caused by medication interactions through combinations of prescription medications supplied at different pharmacies which could be potentially harmful when taken together.

New Note 2 confirms that the publications by the Pharmaceutical Society of Australia could be viewed on its website in 2022.

Item 16 – Section 7

Item 16 corrects the title and date of publications by the Pharmaceutical Society of Australia.

Item 17 – Section 7 (note)

Item 17 corrects an incorrect date of a publication by the Pharmaceutical Society of Australia.

Item 18 – Sections 8 and 9

Item 18 repeals sections 8 and 9 entirely and replaces it with new sections 8 to 15 and a new section 16 under Part 3, which outlines the application, saving and transitional provisions.

New section 8

New section 8 provides that an approved pharmacist must ensure that all pharmacists involved in the dispensing of pharmaceutical benefits at the approved premises, on behalf of the approved pharmacist, are registered pharmacists and must comply with the conditions set out in the Determination. A registered pharmacist is newly defined in section 5 as an individual who is registered to practice as a pharmacist in Australia and does not include a pharmacist who is suspended from practice (see item 9).

New section 9

New subsection 9(1) provides that the approval of a pharmacist under section 90 of the Act to supply pharmaceutical benefits at the premises that are the subject of the approval, does not extend to the supply of pharmaceutical benefits at other (unapproved) premises, except in exceptional circumstances where permission has been granted by the Secretary under section 91A of the Act.

The intent of the new section 9 is to complement the existing provisions in the Act and the Determination regarding the prohibition on supplying at or from premises which are not the subject of approval in Part VII of the Act. It does this through the use of the term ‘purport’ or ‘purported’ supply to deal with situations where supply of a pharmaceutical benefit would be

under Part VII of the Act, except supply that has occurred at or from premises which are not the subject of the pharmacist's approval under section 90 of the Act.

This provision supports the overall purpose of the scheme, which requires each premise involved in the supply of pharmaceutical benefits to be approved (or permitted) by the Secretary. This means an approval granted in respect of particular premises must not be used to supply pharmaceutical benefits at two or more premises simultaneously. It does this by making it a condition of a pharmacist's approval that any other premises cannot be involved in the supply of a pharmaceutical benefit.

The note to new subsection 9(1) is provided to clarify that a reference to the supply of a pharmaceutical benefit 'at' the approved premises means where the person being supplied the benefit is physically present at the approved premises when the prescription is supplied. It is intended to convey that both the pharmacist supplying the benefit and the person receiving the benefit (i.e. generally the patient, the patient's carer or the patient's family member) are located in the same pharmacy premises at the same time (i.e. face-to-face supply).

New subsection 9(2) provides consistency with the primary legislation, by clarifying the intent that pharmaceutical benefits may only be supplied 'from' premises in respect of which a pharmacist is approved, under section 90 of the Act, or 'from' premises in respect of which a permission is in place, under section 91A of the Act. It does this by making it a breach of an approved pharmacist's conditions of approval if the pharmaceutical benefit is supplied 'from' other premises. That is, a pharmaceutical benefit must not be supplied to a person from premises which are not the premises in respect of which the pharmacist is approved. This will not impact supplies made by an online pharmacy to a patient's residential address or supplies based on e-prescriptions sent to a patient's residential address as these supplies are considered to be 'from' the approved premises.

New section 10

New subsection 10(1) provides that a pharmaceutical benefit must not be supplied to a person at or from the premises in respect of which the pharmacist is approved unless all the dispensing steps, outlined in new section 9, have been met. This means if the dispensing of the pharmaceutical benefit was performed by a registered pharmacist who was physically located at other premises when the benefit was dispensed, then the pharmaceutical benefit has not been dispensed at the approved premises and therefore cannot be supplied as a pharmaceutical benefit. For example, a registered pharmacist who is dispensing a pharmaceutical benefit cannot use technology to remotely dispense a pharmaceutical benefit, as the registered pharmacist is required to be physically present at the approved premises when the benefit is dispensed.

New subsection 10(2) provides that for a pharmaceutical benefit to be supplied at or from the premises in respect of which the pharmacist is approved, the pharmaceutical benefit must be at the approved premises at the time it is being dispensed. It is intended to convey that for a ready prepared pharmaceutical benefit, the benefit must be retrieved and labelled at the premises in respect of which the pharmacist is approved. If the benefit is not at the approved premises when any of the dispensing steps are carried out, then it is not considered to have been dispensed at the approved premises. For example, if the benefit is retrieved at the approved premises and transferred to other premises to be labelled, then the benefit has not been dispensed at the approved premises.

New subsection 10(3) provides that for a pharmaceutical benefit to be supplied at or from the premises in respect of which the pharmacist is approved, it must be a registered pharmacist who dispenses, or supervises the dispensing, of the pharmaceutical benefit. A suspended pharmacist or any other pharmacist who is not registered to practice pharmacy in Australia must not dispense, or supervise the dispensing, of the pharmaceutical benefit.

New subsection 10(4) provides that for a pharmaceutical benefit to be supplied at or from the premises in respect of which the pharmacist is approved, the pharmacist dispensing, or directly supervising the dispensing, of the pharmaceutical benefit, must be physically present at the approved premises when each of the dispensing steps are being performed.

The intention of this provision is to convey that a prescription must be dispensed (or supervised) by a person who is suitably qualified as a pharmacist under Australian law and that person must be physically present at the approved premises at the time the prescription is dispensed. That is, the registered pharmacist cannot remotely dispense, or remotely supervise the dispense (via any electronic means or otherwise) the prescription and supply of the pharmaceutical benefit from some other location. This includes requiring the registered pharmacist to see the prescription at the approved premises, unless the supply of the pharmaceutical benefit meets the requirements for supply without a prescription under the Regulations.

Direct supervision is intended to convey that both the registered pharmacist and the person being supervised are both physically present together at the approved premises when each of the dispensing steps is carried out.

If the pharmacist logs into the pharmacy dispensing system remotely, then they are not considered to be physically present at the approved premises when the pharmaceutical benefit is dispensed.

New section 11

New section 11 provides that the registered pharmacist, when dispensing, or directly supervising the dispensing of, a pharmaceutical benefit must see the prescription at the approved premises. The requirement to see the prescription does not apply to medication chart prescriptions.

New Note to new subsection 11(2) is intended to clarify the requirement to ‘see’ the prescription does not apply where the Regulations provide for a pharmaceutical benefit to be supplied without a prescription.

New section 12

New section 12 provides that an approved pharmacist is not entitled to seek an advance payment, or to make a claim for payment, for the supply of pharmaceutical benefits if the benefit was a purported supply, that is a supply made at or from premises which are not approved to supply pharmaceutical benefits.

It also provides that an approved pharmacist is not entitled to seek an advance payment, or to make a claim for payment, for the supply of a pharmaceutical benefit if the supply contravened subsections 10(1) or 11(1). An example of where there is no entitlement is where the benefit is supplied at the approved premises by a registered pharmacist who was not physically present at those premises when the prescription was dispensed (for example, the pharmacist remotely logged into the pharmacy’s dispensing system to dispense the

prescription), then there is no entitlement for the approved pharmacist to seek an advance payment, or to make a claim for payment, for that supply.

New section 13

New section 13 provides that where a pharmaceutical benefit is not supplied, the approved pharmacist can only generate a deferred supply authorisation where it is generated by a registered pharmacist, or under the direct supervision of a registered pharmacist, at the approved premises at the time of generation.

New section 14

New section 14 provides that an approval number, granted to an approved pharmacist under section 16 of the Regulations, must not be used to: dispense a pharmaceutical benefit; purportedly supply a pharmaceutical benefit; prepare a repeat authorisation; or prepare a deferred supply authorisation at any premises other than the approved premises.

New section 15

New section 15 provides that an approved pharmacist must not enter into any arrangement that would facilitate the supply of pharmaceutical benefits to a person at another pharmacy business. For example, the approved pharmacist must not enter into an arrangement whereby prescriptions would be presented by a patient at another pharmacy business and transferred to the approved premises for dispensing and supply, irrespective of whether that arrangement is done with or without the patient's knowledge and consent.

New section 16

New section 16 is under Part 3 of the Amending Instrument, which sets out the saving and transitional provisions relating to the Amending Instrument.

New subsection 16(1) provides that the amendments made in the Amending Instrument apply to approved pharmacists on or after the commencement of the Amending Instrument. That is, they apply to a pharmacist approved prior to the date of commencement in relation to the supply of a pharmaceutical benefit on or after that date.

New subsection 16(2) provides for those approved pharmacist who are the subject of inquiry by the Pharmaceutical Services Federal Committee of Inquiry under section 114 of the Act. The Pharmaceutical Services Federal Committee of Inquiry is the only Committee of Inquiry with several inquiries in progress at the commencement of this instrument.

New subsection 16(3) provides that an approved pharmacist is temporarily exempt from the amending conditions if they are the subject of inquiry by the Pharmaceutical Services Federal Committee of Inquiry, under section 114 of the Act, when the amendments come into effect. That is, if an approved pharmacist was referred, under section 114 of the Act, prior to the amendments coming into effect, then the approved pharmacist will not be subject to the amending conditions until the approved pharmacist receives the Committee's report on findings or is otherwise notified that the inquiry is terminated. While the Act does not provide for this process, it is an administrative process that the Committee undertakes to give pharmacist their report on findings or a notice that the inquiry has terminated prior to the Committee completing their inquiry. Reasons for termination of an inquiry may include where the approved pharmacist is no longer approved to supply pharmaceutical benefits for reasons not related to the inquiry. This could include, but is not limited to, bankruptcy, de-registration or death of the person who is (or was) the approved pharmacist.

Schedule 2 — Consequential Amendments

National Health (Chemotherapy Prescribing) Special Arrangement 2020

Item 1 - Subsection 12(1)

Item 1 amends the *National Health (Chemotherapy Prescribing) Special Arrangement 2020* to change the reference to ‘medication chart’ to have the same meaning as in the Regulations.

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

Item 2 - Section 34A

Item 2 repeals section 34A of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and substitutes it with a new section 34A to clarify that the conditions of approval in the Determination do not apply to the dispensing or supply of a chemotherapy infusion, or a pharmaceutical benefit which is administered by injection or intravesical which is supplied under the Chemotherapy Special Arrangements.

Item 3 - After section 41

Item 3 inserts new section 41A in the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* to clarify that payment for pharmaceutical benefits supplied under the Chemotherapy Special Arrangements can be made even if the supply is not in accordance with the conditions of the pharmacist’s approval.

National Health (Highly Specialised Drugs Program) Special Arrangement 2021

Item 4 - Section 25

Item 4 repeals section 25 of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* and substitutes it with a new section 25 to clarify which Highly Specialised Drugs pharmaceutical benefits are not required to adhere to the conditions of approval.

Item 5 - After section 30

Item 5 inserts new section 30A in the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* to clarify that payment for pharmaceutical benefits supplied under the Highly Specialised Drugs Program Special Arrangements can be made even if the supply is not in accordance with the conditions of the pharmacist’s approval.

National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017

Item 6 - Section 18

Item 6 repeals section 18 of the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* and substitutes it with a new section 18 to clarify that supplies made under the Remote Area Aboriginal Health Services Program Special Arrangements are not required to adhere to the conditions of approval.

Statement of Compatibility with Human Rights

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

National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023

The Amending Instrument 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 purpose of the *National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023* is to amend the *National Health (Pharmaceutical Benefits)(Conditions of approval for approved pharmacists) Determination 2017* (the Conditions of Approved Pharmacists) to prevent an approved pharmacist being involved in the supply of pharmaceutical benefits at premises which are not approved, or making a claim for payment or a claim for an advance payment in respect of pharmaceutical benefits supplied at or from premises which are not the approved premises, unless the Secretary of the Department has granted permission to the pharmacist in respect of those other premises, following disaster or exceptional circumstances.

Section 92A of the *National Health Act* (the Act) sets out the conditions to which a pharmacist, approved to supply pharmaceutical benefits at particular premises, must comply.

The Amending Instrument clarifies the intent that pharmaceutical benefits must only be supplied at or from premises which are approved or at premises authorised by the Secretary, as a result of disaster or exceptional circumstances which prevents supply at the approved premises.

Human Rights Implications

The Amending Instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right to everyone to the enjoyment of the highest attainable standard of physical and mental health. The United Nations Committee on Economic, Social and Cultural Rights (the Committee) has stated that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as a right to be healthy, but rather entails a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Pharmaceutical Benefits Scheme (PBS), which assists with advancement of this human right by providing access to subsidised medicines for people. This is a positive step towards attaining the highest standard of health for all Australians. Ensuring PBS medicines are only dispensed by a pharmacist, or under the direct supervision of a pharmacist, who is registered as a pharmacist in Australia reduces the risk of dispensing errors and accords with the overall purpose and intent of the PBS.

This instrument closely engages with Article 17 of the International Covenant on Civil and Political Rights as it protects a person's privacy by preventing the sharing of prescription information between pharmacies not authorised to be supplying PBS medicines, including the prevention of remote access to a pharmacy by person/s located outside Australia.

Conclusion

This Instrument is compatible with human rights as it advances the protection of human rights.

Mark Butler

Minister for Health and Aged Care