

## EXPLANATORY STATEMENT

### *National Health Act 1953*

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

#### **Authority**

Subsection 92A(1)(f) of the *National Health Act 1953* (the **Act**) provides that the approval of a pharmacist or medical practitioner to supply pharmaceutical benefits is subject to a range of specified conditions. These conditions are set out in paragraphs 92A(1)(a) to (f), with paragraph (f) referring to “any other condition as determined by the Minister”.

The Minister for Health may determine other conditions including, but not limited to, conditions relating to premises that apply to the approval of a person as an approved pharmacist or medical practitioner.

Subsection 92A (1A) of the Act provides that a determination made under paragraph 92A(1) (f) is a disallowable instrument.

On 21 August 2007, the then Minister for Health and Ageing, Tony Abbott, made *National Health (Pharmaceutical Benefits) (Conditions of approval of approved pharmacists) Determination 2007* (PB 42 of 2007) under paragraph 92A (1) (f) of the Act (‘the existing Determination’).

#### **Purpose**

The *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* (‘the Determination’) repeals the existing Determination.

The Determination sets out conditions that must be met by pharmacists approved to supply pharmaceutical benefits (‘approved pharmacists’) relating to:

- professional conduct;
- competency standards for the practice of pharmacy; and
- the circumstances in which an approved pharmacist may claim for payment by the Commonwealth for the supply of a pharmaceutical benefit at or from approved premises.

The Determination commences on the day after it is registered on the Federal Register of Legislation.

A description of each provision in the Determination is contained in the [Attachment](#).

## **Consultation**

During the past three years the Department of Health has undertaken broad consultation on the conditions of approval for pharmacists approved under s90 of the Act with a number of key industry stakeholders including the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Pharmacy Board of Australia, the Consumers Health Forum, the Therapeutic Goods Administration and the Department of Human Services. These consultations supported amendments made on 1 December 2014 to the existing Determination to better clarify the obligations of approved pharmacists against the conditions of their approval. All of these amendments and the conditions contained in the existing determination are retained in this Determination.

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

## ATTACHMENT

### ***NATIONAL HEALTH (PHARMACEUTICAL BENEFITS) (CONDITIONS OF APPROVAL FOR APPROVED PHARMACISTS) DETERMINATION 2017***

#### **Section 1 Name of Determination**

This section provides for the Determination to be referred to as the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*. It may also be cited as Determination No. PB 70 of 2017.

#### **Section 2 Commencement**

This section provides that the Determination commences the day after the Determination is registered on the Federal Register of Legislation.

#### **Section 3 Revocation**

This section revokes Determination No PB 42 of 2007 made by the then Minister for Health and Ageing, Tony Abbot, on 21 August 2007 under subsection 92A(1)(f) of the *National Health Act 1953*.

#### **Section 4 Purpose**

For paragraph 92A (1) (f) of the *National Health Act 1953* (the Act), this Determination sets out conditions that apply to the approval of a person as an approved pharmacist for the purposes of Part VII of the Act (including an approval granted before the commencement of section 92A of the Act and an approval of a person or body referred to in section 83Z of the Act).

*Note* Under subsection 84 (1) of the Act, ***approved pharmacist*** means a person for the time being approved under section 90 of the Act and includes:

- (a) a person treated as having been so approved under any provision of a law of the Commonwealth other than section 91 of the Act; and
- (b) except so far as subsection 90 (3) of the Act is concerned — a person treated as having been so approved under section 91 of the Act.

#### **Section 5 Definitions**

In this determination:

***approved premises*** for an approved pharmacist means premises in respect of which the pharmacist is approved for the purposes of Part VII of the *National Health Act 1953*.

***medication chart prescription*** has the same meaning as in the *National Health (Pharmaceutical Benefits) Regulations 2017*.

***reference time*** means the start of the day the Determination commences.

## Section 6 Standards of practice

This section provides that an approved pharmacist must, in dispensing prescriptions for pharmaceutical benefits and in supplying pharmaceutical benefits:

- (a) comply with all legal requirements for the practice of pharmacy; and
- (b) treat patients with dignity regardless of manner of payment, race, sex, age, nationality, religion, disability or any other factor; and
- (c) comply with the Pharmaceutical Society of Australia's Code of Ethics for Pharmacists 2017, as existing at the reference time; and
- (d) comply with the Pharmaceutical Society of Australia's Professional Practice Standards V5 2017, as existing at the reference time, in relation to each patient, subject to the patient's preparedness to:
  - (i) ensure that the pharmacist has ready access to the patient's medication history; and
  - (ii) provide relevant personal medical information necessary for the pharmacist to individualise patient care; and
  - (iii) authorise medical practitioners and other health care practitioners to release relevant medical information necessary for the pharmacist to act responsibly and reasonably and to individualise patient care; and
  - (iv) allow the pharmacist sufficient time to dispense medications; and
  - (v) follow advice and directions given by the patient's medical practitioner or pharmacist and report any unusual or adverse reactions as soon as possible; and
- (e) maintain a disciplined dispensing procedure that includes:
  - (i) attention to accuracy of product or ingredient selection; and
  - (ii) accuracy of calculations; and
  - (iii) application of accepted techniques for the preparation of pharmaceutical products; and
  - (iv) appropriate packaging and storage; and
  - (v) accuracy of the final product; and
  - (vi) adequate information for the patient.

*Examples for subparagraph (d) (i) of ways of ensuring that a pharmacist has ready access to a patient's medication history*

- Having all prescriptions dispensed at a single pharmacy
- Providing the pharmacist with a patient-held medication record form from another pharmacy or a prescriber
- Authorising the transfer of the patient's medication history from another pharmacy.

Note: The Code of Ethics for Pharmacists 2017 and the Professional Practice Standards 2017 could in 2017 be viewed on the Pharmaceutical Society of Australia's website (<http://www.psa.org.au>).

## Section 7 Continuing education

This section provides that an approved pharmacist must maintain the currency of his or her pharmaceutical knowledge in accordance with the Pharmaceutical Society of Australia's National Competency Standards Framework for Pharmacists in Australia 2017, as existing at the reference time.

Note: The National Competency Standards Framework for Pharmacists in Australia 2017 could in 2017 be viewed on the Pharmaceutical Society of Australia's website (<http://www.psa.org.au>).

## **Section 8 Other pharmacists at pharmacy**

A person who is an approved pharmacist in respect of a pharmacy at particular premises must ensure that a pharmacist:

- (a) who is not an approved pharmacist; and
  - (b) who supplies pharmaceutical benefits at or from those premises;
- complies with the conditions set out in sections 5 and 6.

## **Section 9 Claims for payment**

- (1) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to the supply of a pharmaceutical benefit unless it was supplied at or from approved premises for the pharmacist.
- (2) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to the supply of a pharmaceutical benefit if that pharmaceutical benefit was never at approved premises for the pharmacist.
- (3) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to the supply of a pharmaceutical benefit unless the pharmacist, or an agent of the pharmacist, was present at approved premises for the pharmacist at the time the pharmaceutical benefit was dispensed.
- (4) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to the supply of a pharmaceutical benefit on the basis of a prescription (other than a medication chart prescription) unless the pharmacist, or an agent of the pharmacist, has seen the prescription at approved premises for the pharmacist.

Note: A supply in accordance with subsection 89A(1) of the *National Health Act 1953* (supply of pharmaceutical benefit without prescription) or on an order lodged under regulation 33 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (prescriber bag supplies) would not be a supply on the basis of a prescription.

- (5) An approved pharmacist must not make a claim for payment from the Commonwealth in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription unless the pharmacist, or an agent of the pharmacist, has seen the chart or a copy of the chart containing the prescription at approved premises for the pharmacist.
- (6) Subsections (2) to (5) do not limit subsection (1).
- (7) This section does not apply in relation to the supply of a pharmaceutical benefit in respect of which the pharmacist is entitled to a payment in accordance with subsection 99(3A) of the *National Health Act 1953* (supply of pharmaceutical benefit before obtaining approval).

Note: See also subsection 100(3) of the *National Health Act 1953* (instruments made for the purposes of Part VII of that Act have effect subject to special arrangements).

## **Statement of Compatibility with Human Rights**

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

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

This Legislative 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 this legislative instrument, made under subsection 92A(1)(f) of the Act, is to repeal and replace entirely the previous determination, *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007*.

To supply pharmaceutical benefits a pharmacist must be approved under section 90 of the Act and is then subject to the conditions of approval set out in section 92A. Subsection 92A(1)(f) allows the Minister to determine any other condition, including, but not limited to, conditions relating to premises.

This remade Determination updates obsolete text and terminology to ensure approved pharmacists can better meet their conditions of approval while retaining all the conditions of approval set out in the previous determination including references to professional practice standards and codes of ethics with which approved pharmacists are required to adhere. The remade Determination also retains conditions that restate the position already established within the Act and restrict the claiming for the supply of a pharmaceutical benefit to an approved pharmacist supplying a pharmaceutical benefit at or from premises for which the pharmacist holds an approval.

### **Human rights implications**

This legislative instrument engages Articles 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 of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access for people to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

### **Conclusion**

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

**Greg Hunt**  
**Minister for Health**  
**Minister for Sport**