

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health and Ageing

National Health Act 1953

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007

Subsection 92A (1) of the *National Health Act 1953* ('the Act') provides that the approval of a pharmacist or a 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".

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

On 10 November 1995, the then Minister for Human Services and Health, Dr Carmen Lawrence, made Determination No. PB 16 of 1995 under paragraph 92A (1) (f) of the Act ('the existing Determination').

The *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007* ('the Determination') revokes and replaces 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 and pharmacy practice standards in supplying pharmaceutical benefits, and pharmacy competency standards in education.

The Determination also reflects amendments made to the Act by Part 3 of Schedule 1 to the *Health Legislation Amendment (Podiatric Surgery and Other Matters) Act 2004* ('the Amending Act').

Part 3 of Schedule 1 to the Amending Act amended the Act to ensure that the death of an approved pharmacist does not affect continued community access to pharmaceutical benefits. These amendments enable a person who is, or is likely to become, an executor or administrator of the estate of a deceased approved pharmacist, to apply for permission under section 91 of the Act to supply pharmaceutical benefits at or from the premises in respect of which the deceased pharmacist had been approved. The Amending Act amended the definition of "approved pharmacist" in subsection 84(1) of the Act to include persons treated as approved pharmacists under section 91 of the Act.

The Determination clarifies that as persons treated as approved pharmacists under section 91 of the Act are "approved pharmacists", the conditions set out in the Determination also apply to these persons.

The Determination also makes clear that a person who is an approved pharmacist in respect of particular premises must ensure that a pharmacist who is not an approved pharmacist, and who supplies pharmaceutical benefits at or from those premises, also complies with the conditions set out in the Determination.

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

Details of the Determination are set out in the Attachment.

The Pharmacy Guild of Australia, the body that represents a majority of pharmacy owners, and the Pharmaceutical Society of Australia, the professional organisation for pharmacists, have been consulted on this matter. Medicare Australia has the delegated authority for approval of pharmacists to supply pharmaceutical benefits and has also been consulted.

**DETAILS OF THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS)
(CONDITIONS OF APPROVAL FOR APPROVED PHARMACISTS)
DETERMINATION 2007**

Section 1 provides for the Determination to be referred to as the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007*.

Section 2 provides for the Determination to commence on the day after it is registered on the Federal Register of Legislative Instruments.

Section 3 revokes determination No. PB 16 of 1995 made by the then Minister for Human Services and Health, Dr Carmen Lawrence, on 10 November 1995 under subsection 92A(1)(f) of the *National Health Act 1953* ('the Act').

Section 4 specifies that the conditions set out in the Determination apply to the approval of a person "as an **approved pharmacist**".

To ensure consistency with the Act and to remove any uncertainty as to its meaning, the Note at section 4 inserts the definition of 'approved pharmacist' from subsection 84(1) of the Act. This makes clear that any reference to an 'approved pharmacist' in the Determination means a person approved under section 90 of the Act and includes any person treated as having been so approved under section 91 of the Act, and any person treated as having been so approved under any provision of a law of the Commonwealth other than section 91 of the Act.

Section 5 provides the conditions with which an approved pharmacist must comply in dispensing and supplying pharmaceutical benefits. In summary, these conditions require that an approved pharmacist must:

- comply with the legal requirements for practicing pharmacy, including ongoing education requirements in those States or Territories which have them (paragraph 5(a));
- treat patients with dignity and without discrimination (paragraph 5(b));
- comply with the Pharmaceutical Society of Australia's Code of Professional Conduct (paragraph 5(c));
- comply with the Pharmaceutical Society of Australia's Professional Practice Standards (paragraph 5(d)); and
- maintain a disciplined dispensing procedure (paragraph 5(e)).

Section 5 makes clear that compliance with the Pharmaceutical Society of Australia's Professional Practice Standards (paragraph 5(d)) is subject to a patient's preparedness to:

- provide the pharmacist with access to the patient's medication history and medical history (see subparagraphs 5(d)(i), (ii) and (iii));
- allow the pharmacist sufficient dispensing time (see subparagraph 5(d)(iv)); and
- follow advice given by the pharmacist and the patient's medical practitioner and report adverse reactions (see subparagraph 5(d)(v)).

Section 5 also lists examples of ways of ensuring that a pharmacist has ready access to a patient's medication history for the purpose of subparagraph 5(d)(i) of the Determination.

The Note at section 5 provides information on obtaining the Pharmaceutical Society of Australia's Code of Professional Conduct and Professional Practice Standards referred to in section 5.

Section 6 provides that an approved pharmacist must maintain the currency of his or her pharmaceutical knowledge in accordance with the Pharmaceutical Society of Australia's Competency Standards 2003. These standards refer to skills and attributes gained through knowledge, experience and ongoing education enabling an individual to practice as a pharmacist.

The Note at section 6 provides information on obtaining the Pharmaceutical Society of Australia's Competency Standards for Pharmacists in Australia 2003.

Section 7 makes clear that a person who is an approved pharmacist in respect of particular premises must ensure that a pharmacist who is not an approved pharmacist, and who supplies pharmaceutical benefits at or from those premises, also complies with the conditions set out in sections 5 and 6 of the Determination.