

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2010 No. 231**

#### *National Health Act 1953*

#### *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 3)*

Section 140 of the *National Health Act 1953* (the Act) provides, in part, that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which 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.

Part VII of the Act provides for the supply of drugs and medicinal preparations under Commonwealth subsidy (commonly known as the Pharmaceutical Benefits Scheme (PBS)), by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

The Regulations are part of the implementation of the *Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010* (the Amendment Act) which commenced on the Royal Assent on 12 April 2010 and provides for new arrangements to enhance and expand the role of midwives and nurse practitioners, allowing them to take a greater role in providing quality health care.

The Amendment Act amends both the Act and the *Health Insurance Act 1973* to enable nurse practitioners and appropriately qualified and experienced midwives to request appropriate diagnostic imaging and pathology services for which Medicare benefits may be paid. It allows these health professionals to be authorised as PBS prescribers able to prescribe certain medicines under the PBS. Secondary legislation will also provide for such matters as the creation of new Medicare items and referrals under the Medicare Benefits Schedule (MBS).

Access to MBS services and PBS subsidised medicines is available to patients of appropriately qualified and experienced midwives and nurse practitioners from 1 November 2010. To be authorised to prescribe under the PBS, midwives and nurse practitioners need to be able to prescribe medicines under state or territory law, within the practitioner's scope of practice.

The purpose of the Regulations is to amend the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to allow authorised midwives and authorised nurse practitioners to prescribe certain medicines for supply under the PBS in line with changes made to the Act by the Amendment Act.

The Regulations amend the Principal Regulations to give effect to new PBS arrangements that are consistent with the Act (as amended by the Amendment Act) by:

- adding definitions for 'authorised midwife' and 'authorised nurse practitioner';
- applying the processes required for the application, approval and issuing of approval numbers (which are numbers issued to PBS prescribers when approved to prescribe under the PBS) to midwives and nurse practitioners;
- applying the requirements for prescription forms and for the writing of prescriptions to PBS prescriptions written by authorised midwives and authorised nurse practitioners;

- applying the requirements relating to the obtaining and supplying of pharmaceutical benefits in limited circumstances (emergency drug supplies – emergency bag) to authorised midwives and authorised nurse practitioners; and
- enabling authorised midwives and authorised nurse practitioners to write PBS prescriptions for pharmaceutical benefits for supply on one occasion instead of directing a repeated supply by providing the circumstances in which this may occur.

Details of the Regulations are set out in the Attachment.

Consultation regarding implementation of the arrangements for access by patients to midwife and nurse practitioner Medicare services and PBS prescribing occurred via advisory groups established to advise on specific issues and technical aspects. The advisory groups included practitioners from relevant medical and health professions, with experience in midwifery, nursing, general practice, obstetrics, and representatives from registration bodies, state and territory health services, regional and remote health services, Indigenous populations, and consumers. Advice included advice on Medicare and PBS eligibility, collaborative arrangements with medical professionals, authorisation as PBS prescribers, and medicines suitable for PBS prescribing.

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 *Legislative Instruments Act 2003*.

Regulations 1 to 3 and Schedule 1 which contain the provisions relating to approval as an authorised midwife and authorised nurse practitioner, commence on the later of 1 July 2010 or the day following registration. Schedule 1 commences prior to 1 November 2010 to assist Medicare Australia to allot approval numbers to prepare for patient access to subsidised medicines under the PBS on 1 November 2010. Schedule 2, which makes certain technical changes to allow authorised midwives and authorised nurse practitioners to prescribe certain medicines for supply, commences on 1 November 2010.

**Details of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 3)*****Regulation 1 – Name of Regulations**

This regulation provide that the title of the Regulations is the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No 3)*.

**Regulation 2 – Commencement**

This regulation provides for regulations 1 to 3 and Schedule 1 to commence on the later of 1 July 2010, or the day following registration, and for Schedule 2 to commence on 1 November 2010.

**Regulation 3 – Amendment of *National Health (Pharmaceutical Benefits) Regulations 1960***

This regulation provides that the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) are amended as set out in Schedules 1 and 2.

**Schedule 1 – Amendments****Item [1] – Subregulation 5(1), after definition of approved supplier**

This item inserts new definitions into subregulation 5(1) for the terms ‘authorised midwife’ and ‘authorised nurse practitioner’. These terms are also used in the *National Health Act 1953* (the Act) and their use in the Principal Regulations relies on the definitions within subsection 84(1) of the Act.

**Item [2] – Regulation 8AA**

This item substitutes the current regulation 8AA with a new regulation 8AA. The new regulation 8AA maintains the existing requirement regarding applications for approval as an authorised optometrist and also inserts new requirements that an application for approval as an authorised midwife (under subsection 84AAF(1) of the Act) or as an authorised nurse practitioner (under subsection 84AAJ(1) of the Act) must also be made in a form acceptable to the Secretary of the Department of Health and Ageing (the Secretary).

**Item [3] – After paragraph 8A(1)(aa)**

This item inserts new paragraphs 8A(1)(ab) and 8A(1)(ac) into the Principal Regulations. Paragraph 8A(1)(ab) provides for the allocation of an approval number to an eligible midwife, if they have been approved by the Secretary under section 84AAF of the Act. Paragraph 8A(1)(ac) provides for the allocation of an approval number to an eligible nurse practitioner, if they have been approved by the Secretary under section 84AAJ of the Act.

**Schedule 2 – Amendments commencing on 1 November 2010****Item [1] – Subregulation 13(2)**

Regulation 13 allows the Minister to vary the application of the determination in force under paragraph 85A(2)(a) or (b) of the Act (regarding the maximum number of repeats or maximum quantity of units that can be prescribed) in relation to a person to whom this regulation applies. Subregulation 13(2) provides the class of persons to whom regulation 13 applies.

This item omits the phrase ‘medical practitioner or an authorised optometrist (a *practitioner*)’ from subregulation 13(2) and insert the term ‘practitioner’. This change extends the operation of regulation 13 to authorised midwives and authorised nurse practitioners due to the effect of the new internal definition within regulation 13 of ‘practitioner’ at subregulation 13(8) (see item [2] below).

**Item [2] – After subregulation 13(7)**

This item inserts a new subregulation 13(8) which provides a new internal definition of ‘practitioner’ for the purposes of regulation 13. The subregulation provides that in regulation 13, the term ‘practitioner’ covers authorised optometrists, medical practitioners, authorised midwives and authorised nurse practitioners.

**Item [3] – Part IV, heading**

This item substitutes the Part IV heading, ‘Supply of pharmaceutical benefits by medical practitioners’ with ‘Supply of pharmaceutical benefits by medical practitioners, authorised midwives and authorised nurse practitioners’, which reflects that the operation of Part IV has been extended to authorised midwives and authorised nurse practitioners.

**Item [4] – Regulations 15 to 18**

Part IV of the Principal Regulations set out the requirements relating to the supply of pharmaceutical benefits by medical practitioners in limited circumstances (the emergency drug supply provisions).

This item substitutes the existing regulations 15 to 18 relating to the supply of pharmaceutical benefits by medical practitioners with new regulations 14 to 18, in order to extend the operation of Part IV of the Principal Regulations to authorised midwives and authorised nurse practitioners. The purpose of this item is to apply the emergency drug supply provisions to authorised midwives and authorised nurse practitioners in the same way as the existing provisions apply to medical practitioners.

*Regulation 14 – Definition*

‘Practitioner’ is used throughout the new regulations 15 to 18 where ‘medical practitioner’ was used in the existing regulations 15 to 18. New regulation 14 provides a new internal definition of ‘practitioner’ for the purposes of Part IV which covers medical practitioners, authorised midwives and authorised nurse practitioners.

*Regulation 15 – Practitioners not authorised under sections 93 and 93AA*

Regulation 15, as amended by this item, prevents a medical practitioner, authorised midwife or authorised nurse practitioner from supplying pharmaceutical benefits under the emergency drug supply provisions whilst he or she is practising his or her profession on a ship.

*Regulation 16 – Obtaining benefits by practitioners under sections 93 and 93AA*

Regulation 16, as amended by this item, sets out the requirements that a medical practitioner, an authorised midwife or an authorised nurse practitioner must satisfy to supply pharmaceutical benefits under the emergency drug supply provisions.

*Regulation 17 – Supply of pharmaceutical benefits by approved pharmacists under sections 93 and 93AA*

Regulation 17 contains a strict liability offence provision which applies to an approved pharmacist. This item amends regulation 17 to ensure that the offence provision also applies when pharmaceutical benefits are supplied under the emergency drug supplies provisions by authorised midwives and authorised nurse practitioners.

Regulation 17, as amended by this item, provides that an approved pharmacist commits an offence if he or she:

- supplies a pharmaceutical benefit on an order lodged under regulation 16; and
- neither of the following circumstances applies;
  - the pharmacist knows the practitioner whose signature appear on the order;
  - if the pharmacist does not know the practitioner whose signature appears on the order:
    - the person who lodged the order has given the pharmacist the full name and address of the practitioner; and
    - if the practitioner is a medical practitioner, the person who lodged the order has given the practitioner's medical registration number to the pharmacist; and
    - in relation to a practitioner who is an authorised midwife or an authorised nurse practitioner, the person who lodged the order has given the pharmacist the number that was allotted to the approval of that practitioner by the Secretary under subregulation 8A(1); and
    - the pharmacist writes the details contained in the previous three dot points on the order.

The penalty for the strict liability offence is 0.4 penalty units.

*Regulation 18 – Payment for pharmaceutical benefits supplied under section 93 and 93AA*

Regulation 18, as amended by this item, provides that an approved pharmacist who has supplied a pharmaceutical benefit to a medical practitioner, authorised midwife or authorised nurse practitioner for the purpose of the emergency drug supplies provisions is entitled to payment from the Commonwealth at such rate and subject to such conditions as determined by the Minister and applicable at the time of the supply.

**Item [5] – Paragraph 19(1)(ca)**

Regulation 19 sets out the requirements for writing prescriptions under the PBS. Regulation 19 does not require amendment in order to be able to apply to authorised midwives and authorised nurse practitioners, except in relation to paragraphs 19(1)(ca) and (h).

This item omits the phrase 'in the case of a participating dental practitioner or an authorised optometrist' from paragraph 19(1)(ca) and insert the phrase 'for a participating dental practitioner, authorised optometrist, authorised midwife or authorised nurse practitioner'.

The effect of this amendment is that when an authorised midwife or an authorised nurse practitioner writes a PBS prescription, he or she must state in that prescription the number allotted to his or her approval under regulation 8A.

**Item [6] – Paragraph 19(1)(h)**

This item omits the term 'practitioner' from paragraph 19(1)(h) and insert the phrase 'practitioner, authorised midwife or authorised nurse practitioner'.

The effect of this amendment be that if, under regulation 24, an authorised midwife or authorised nurse practitioner directs the supply of a certain quantity or number of units of a pharmaceutical benefit on one occasion instead of directing a repeated supply, that authorised midwife or authorised nurse practitioner must write on the prescription 'Reg 24' or 'Regulation 24'.

**Item [7] – Regulation 24**

This item omit 'A' from regulation 24 and insert '(1) A' to provide for the insertion of new subregulation 24(2) (see item [8] below).

**Item [8] – Regulation 24**

This item insert a new subregulation 24(2) which provide for the circumstances in which an authorised midwife or an authorised nurse practitioner may, pursuant to subsection 88(6A) and (6B) of the Act, direct the supply of a certain quantity or number of units of a pharmaceutical benefit on one occasion instead of directing a repeated supply. The circumstances prescribed in the new subregulation 24(2) for authorised midwives and authorised nurse practitioners mirror the existing circumstances prescribed for medical practitioners.

**Item [9] – Subregulation 28(1)**

Subregulation 28(1) allows prescriptions for the supply of a pharmaceutical benefits marked and initialled as 'URGENT' by the medical practitioner or participating dental practitioner writing the prescription to be presented to an approved pharmacist. A patient is then entitled to be supplied with that pharmaceutical benefit outside of normal trading hours.

This item omit the phrase 'medical practitioner or participating dental practitioner' from subregulation 28(1) and insert 'medical practitioner, participating dental practitioner, authorised midwife or authorised nurse practitioner' in order to extend subregulation 28 to include prescriptions marked and initialled as 'URGENT' by an authorised midwife or an authorised nurse practitioner who wrote the prescription.

Subregulation 28(2) is a strict liability offence provision. It is not amended by item [9], but its scope is broadened by the amendment to subregulation 28(1). An approved pharmacist commits an offence if he or she is presented with a prescription under subregulation 28(1); any charge lawfully demanded for the prescription is paid; and the approved pharmacist does not supply the pharmaceutical benefit as soon as practicable.

**Item [10] – Paragraph 36(2)(c)**

Subregulation 36(1) requires a pharmaceutical benefit supplied by an approved supplier to be labelled with the words 'full cost' followed by the full cost of the pharmaceutical benefit.

Subregulation 36(2) provides for exceptions from the requirement in subregulation 36(1). The existing paragraph 36(2)(c) contains an exception for pharmaceutical benefits obtained under subsection 93(2) of the Act (i.e. a medical practitioner's 'doctor's bag').

This item insert 'or 93AA(2)' after '93(2)' in paragraph 36(2)(c). This amendment extend the exception in paragraph 36(2)(c) to include pharmaceutical benefits obtained under subsection 93AA(2), which relates to emergency drug supplies for authorised midwives and authorised nurse practitioners.