EXPLANATORY STATEMENT

Select Legislative Instrument 2010 No. 294

National Health Act 1953

National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment Regulations 2010 (No. 1)

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 by the Act to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Division 4C of Part VII of the Act enables fees to be charged for certain services provided by the Commonwealth Government (the Commonwealth) in order to recover the cost to the Commonwealth of providing those services. Those services relate to the exercise of certain powers of the Minister for Health and Ageing (the Minister) under section 9B of the Act (which relates to the National Immunisation Program (NIP)) and under Part VII of the Act (which relates to the Pharmaceutical Benefits Scheme (PBS)). The services include the functions of the Pharmaceutical Benefits Advisory Committee (PBAC) and its sub-committees, the functions of the Pharmaceutical Benefits Pricing Authority, and related functions performed by officers and administrative staff of the Department of Health and Ageing (the Department) and by contractors and sub-contractors of the Department.

Section 99YBA of the Act provides for regulations to set out the fees payable for those services, as well as other matters relating to the payment of those fees and the provision of those services, including some consequences of failing to pay a fee. The *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* (the Principal Regulations) commenced operation on 1 January 2010.

The Regulations amend the Principal Regulations relating to amendments to be made to the Act by Schedule 6 to the *National Health (Pharmaceuticals Benefits Scheme) Act 2010* (the Amending Act).

The Principal Regulations currently prescribe application categories, fees and application procedures to applicants seeking a new or amended inclusion of products in the PBS or the NIP. The Principal Regulations also provide for exemption from fees, waiver of fees, and for review rights and procedures.

Schedule 6 to the Amending Act will modify provisions of the Act concerning PBS-listed drugs which are made available under special arrangements pursuant to section 100 of the Act.

In particular, Schedule 6 will remove the term ‘special pharmaceutical product’ from the Act, as all listed drugs will now be pharmaceutical benefits declared under section 85. The Regulations remove all references to ‘special pharmaceutical product’ from the Principal Regulations in line with this change.

The Regulations also add references to possible new applications to the PBAC, and change references to sections in the Act because they will be re-numbered by the Amending Act.

Details of the Regulations are included in the Attachment.

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

The Regulations commence on the day on which Schedule 6 to the Amendment Act commences.

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

Consultation

Extensive consultation occurred during the development of the Principal Regulations, mainly through two peak pharmaceutical industry bodies, Medicines Australia and the Generic Medicines Industry Association of Australia. However, consultation also occurred with specific companies and organisations concerning some particular elements of the cost recovery regulations (eg: treatment of applications for low volume important listings). Other stakeholders consulted included PBS prescribers (such as the Australian Medical Association), consumers (such as the Consumers' Health Forum and Palliative Car Australia) and pharmacists (The Pharmacy Guild of Australia).

The amendments to the Regulations in this instrument are machinery in nature, and consequential to changes made to the *National Health Act 1953* during 2010 dealing with further Pharmaceutical Benefits Scheme (PBS) pricing reform, and prescribing by midwives and nurse practitioners. Consultation regarding further PBS pricing reforms occurred with peak pharmaceutical industry bodies, and was finalised through negotiations with Medicines Australia. Consultation for arrangements for midwives and nurse practitioners as PBS prescribers occurred through advisory groups established in connection with specific issues. The advisory groups included practitioners from medical and allied health professions, with experience in midwifery, nursing, general practice and obstetrics. They also included representatives from registration bodies, state and territory health services, regional and remote health services, indigenous populations, and consumers. As the amendments in these Regulations are consequential to changes to the *National Health Act 1953*, no further specific consultations were required.

ATTACHMENT

Details of the *National Health (Pharmaceuticals and Vaccines – Cost Recovery Amendment Regulations 2010 (No. 1)*

The Regulations expand item 2.5 of Part 2 of Schedule 1 to the Principal Regulations. The effect is that applications to PBAC for a recommendation that the Minister determine (or vary an existing determination about) the manner of administration of a pharmaceutical benefit, or that a pharmaceutical benefit is only able to be supplied under a section 100 special arrangement, now falls within the scope of the Principal Regulations. Consequential to these changes, and the removal of the term 'special pharmaceutical product', items 2.12-2.14 of Part 2 of Schedule 1 are removed from the Principal Regulations, as they are now redundant.

Schedule 6 of the Amending Act will replace existing subsections 85(2A) and 85(2AA) in the Act with subsections 85(7) and 101(4AAA) respectively, without changing the meaning of the provisions. The Regulations alter all existing references in the Principal Regulations from subsections 85(2A) and 85(2AA) to subsections 85(7) and 101(4AAA) to reflect this change. The Regulations also alter the reference to subsection 85(2A) in paragraph 5.1(1)(i) of the Principal Regulations to subsection 101(4AAA) rather than subsection 85(7) as the earlier reference should have been to subsection 85(2AA).

Section 93 of the Act provides for pharmaceutical benefits to be supplied by medical practitioners from an emergency bag. Section 93AA of the Act, which was inserted by the *Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010*, allowed for authorised midwives and authorised nurse practitioners to supply pharmaceutical benefits from their own emergency bags. The Regulations extend the reference in the Principal Regulations to the supply of a pharmaceutical benefit under section 93 of the Act to encompass the supply under section 93AA as well.