

EXPLANATORY STATEMENT

Select Legislative Instrument 2011 No. 29

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment Regulations 2011 (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 to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the Regulations is to amend regulation 37HA of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to insert a new entity to whom responsible persons are to provide price disclosure information required under the Act and Principal Regulations.

Part VII Division 3B of the Act deals with price disclosure. The price disclosure requirements apply to all non-exempt brands of pharmaceutical items that have a drug on F2 formulary. Pharmaceutical Benefits Scheme drugs may be placed on the F1 or F2 formulary, which provides a different treatment under the Act, mainly for pricing purposes.

The F1 formulary contains drugs that have only one brand of each form and strength listed on the PBS; and are not interchangeable at the patient level with a drug that has multiple brands listed on the PBS (i.e. not part of a therapeutic group that has multiple brands).

The F2 formulary contains all drugs (excluding single brand combination drugs) that do not meet the criteria for F1 that is multi-branded pharmaceutical items; and drugs which are in therapeutic groups because that are interchangeable with other drugs that have multiple brands.

Price disclosure statutory price reductions occur as a result of the price being adjusted based on information collected from responsible persons about the brands of pharmaceutical items.

Paragraph 99ADC(1)(a) of the Act requires responsible persons to provide price disclosure information to a prescribed person or entity.

The Regulations prescribe Australian Healthcare Associates Pty Ltd as the entity to whom responsible persons are to provide price disclosure information.

Australian Healthcare Associates Pty Ltd provides assistance to the Minister for Health and Ageing (the Minister) (or delegate) by providing ongoing administration of price disclosure, including collecting and collating data submissions from pharmaceutical manufacturers, undertaking price disclosure calculations, and result notifications for submission to and consideration by the Minister (or delegate). Australian Healthcare Associates Pty Ltd was selected to provide this service following an open tender process.

The Regulations also provide that if written notice is received by a responsible person from the Department to this effect, price disclosure information is not to be provided to Australian Healthcare Associates Pty Ltd, and is to be provided to the Assistant Secretary, Pharmaceutical Evaluation Branch, Pharmaceutical Benefits Division, Department of Health and Ageing. This is to ensure that responsible persons have a prescribed person or entity to provide price disclosure information to, in the unlikely event that Australian Healthcare Associates Pty Ltd is not available.

The Act specifies no conditions that need to be met 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*.

The Regulations commence the day after registration on the Federal Register of Legislative Instruments.

Consultation

The entity, Australian Healthcare Associates, was selected from an open tender process issued by the Department of Health and Ageing on 17 July 2010 seeking the provision of data collection and processing services to support the ongoing requirements of Expanded and Accelerated Price Disclosure.

During this open tender process and the amendment of Regulation 37HA, the Department did not consult with any stakeholders with an interest in Expanded and Accelerated Price Disclosure.