

EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 55

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 1)

Section 140 of the *National Health Act 1953* (the Act) provides 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 regulation is to amend regulation 37HA of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) to change a prescribed person to whom responsible persons are to provide the price disclosure information required under the Act and the Principal Regulations.

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

Subregulation 37HA(1) of the Principal Regulations currently prescribes Australian Healthcare Associates Pty Ltd as the entity to whom responsible persons are to provide price disclosure information. Subregulation 37HA(2) of the Principal Regulations provides that if written notice is received by a responsible person from the Department, the price disclosure information is instead to be provided to the Assistant Secretary, Pharmaceutical Evaluation Branch, Pharmaceutical Benefits Division, Department of Health and Ageing. The regulation updates this reference to the First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing.

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

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences the day after registration on the Federal Register of Legislative Instruments.

Consultation:

This instrument affects pharmaceutical companies with medicines listed on the PBS and that are subject to price disclosure. Pharmaceutical companies are required to provide price disclosure information to Australian Healthcare Associates Pty Ltd. However, on written request from the Department, pharmaceutical companies must provide this information to the First Assistant Secretary, Pharmaceutical Benefits Division.

During the amendment of Regulation 37HA, the Department did not consult with any stakeholders with an interest in price disclosure as this change is a minor administrative amendment that will have little or no impact on stakeholders.

Authority: Section 140 of the
National Health Act 1953

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 1)

This Bill/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 Bill/Legislative Instrument

The purpose of the Instrument is to amend regulation 37HA of the *National Health (Pharmaceutical Benefits) Regulations 1960* to change a prescribed person to whom responsible persons are to provide price disclosure information.

Human rights implications

This Bill/Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Bill/Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Tanya Plibersek
Minister for Health