EXPLANATORY STATEMENT

National Health Reform Act 2011

Direction to the Independent Hospital Pricing Authority on the performance of its functions under section 226 of the *National Health Reform Act 2011* - No. 1/2014

Authority

This Instrument is made under subsection 226(1) of the *National Health Reform Act 2011* (the Act), which provides that the Minister may give directions to the Independent Hospital Pricing Authority (IHPA) in relation to the performance of its functions and exercise of its powers. Section 131 of the Act sets out the functions of the IHPA, which include determining the national efficient price for health care services provided by public hospitals where the services are funded on an activity basis: subsection 131(1)(a).

This Instrument operates by directing the IHPA in relation to the performance of its functions and the exercise of its powers. Under subsection 226(4) of the Act, the IHPA must comply with a direction made under subsection 226(1).

Purpose

This Instrument directs the IHPA to determine the costs for the refined list of items associated with conducting clinical trials in Australia (above and beyond the standard costs of care). This work will help assess the true cost of clinical trial activity and will be an invaluable guide for clinical trial sponsors and public institutions as they plan for future clinical trials.

Background

This Instrument gives effect to an agreement by the Standing Council on Health to implement a recommendation from the 8 November 2013 meeting regarding agenda item 2.2 (4). The recommendation proposes that the IHPA develop a table of standardised costs associated with conducting clinical trials in Australia.

Details

Subsection 226(3) of the Act provides that a direction made under subsection 226(1) must:

(a) be of a general nature only; and
(b) not be a direction to change:
    i. a particular national efficient price for health care services provided by public hospitals; or
    ii. a particular efficient cost for health care services provided by public hospitals.

This Instrument is of a general nature only and the costs will be used as a guide for contract negotiations. It does not direct the IHPA to change a particular national efficient price for health care services provided by public hospitals or a particular efficient cost for health care services provided by public hospitals between hospitals and sponsors.

This Instrument directs the IHPA to, as far as possible, consider the actual activity of a clinical trial item and cost-recovery principles in its determination of standard costs.

Consultation

Subsection 226(2) of the Act provides that the Minister must consult with the Standing Council on Health (now known as the Council of Australian Governments Health Council) before giving a direction. Subsection 230(1) specifies the meaning of *Standing Council on Health* to be as follows:

"The ***Standing Council on Health*** is (subject to subsection (2)) the Ministerial Council by that name, or, if there is no such Ministerial Council, the standing Ministerial Council established or recognised by COAG whose members include all Ministers in Australia having portfolio responsibility for health."

The Minister has written to State and Territory health ministers, outlining his intention to issue a direction under subsection 226(1) of the Act.

This Instrument relates solely to the functions and duties of the IHPA. The activity that will be undertaken is not regulatory in nature. As such, a Regulation Impact Statement is not required.

This Instrument commences the day after registration on the Federal Register of Legislative Instrument. This Direction is a legislative instrument for the purposes of the *Legislative Instruments Act 2003* and under the provisions of section 44 of this Act the Instrument is not subject to disallowance.

Statement of Compatibility with Human Rights

A statement of compatibility with human rights has not been prepared as under section 9 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, a statement of compatibility with human rights is only required for disallowable instruments.