EXPLANATORY STATEMENT

National Health Reform Act 2011

DIRECTION FROM THE MINISTER FOR HEALTH AND AGEING TO THE INDEPENDENT HOSPITAL PRICING AUTHORITY UNDER SUBSECTION 226(1) OF THE NATIONAL HEALTH REFORM ACT 2011

1. This Instrument is made under subsection 226(1) of the *National Health Reform Act 2011* ('the Act').
2. This Instrument operates by directing the Independent Hospital Pricing Authority ('the Pricing Authority') in relation to the performance of its functions and the exercise of its powers.
3. Section 131 of the Act sets out the Pricing Authority's functions. These include determining the national efficient price for health care services provided by public hospitals where the services are funded on an activity basis: s 131(1)(a).
4. Specifically, this Instrument directs the Pricing Authority to determine the national efficient price for a list of standard items associated with conducting clinical trials in Australia.
5. This work will help to 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.
6. Subsection 226(1) of the Act provides that the Minister may give directions to the Pricing Authority in relation to the performance of its functions and the exercise of its powers.
7. Subsection 226(2) provides that the Minister must consult with the Standing Council on Health before giving a direction under subsection (1).
8. 'Standing Council on Health' means the Council described in Section 230 of the Act.
9. Subsection 226(3) of the Act, provides that a Direction made under subsection (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.
10. Under subsection 226(4) of the Act, the Pricing Authority must comply with a Direction made under subsection (1).

11. The purpose of this Instrument is to give effect to an agreement of the Standing Council on Health to implement a recommendation of the 2011 Clinical Trials Action Group report: *Clinically competitive: boosting the business of clinical trials in Australia*.
12. This Instrument is of a general nature only and does not direct the Pricing Authority 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.
13. This Instruments directs the Pricing Authority to, as far as possible, consider the actual activity of a standard clinical trial item and cost-recovery principles in its determination of a national efficient price.

Commencement

14. Pursuant to subsection 12(1)(d) of the *Legislative Instruments Act 2003,* this Instrument commences the day after the day it is registered.

Consultation

15. Subsection 226(2) of the Act provides that the Minister must consult with the Standing Council on Health before giving a direction under subsection (1).
16. The Minister has previously written to her State and Territory counterparts, outlining her intention to issue a direction under subsection 226(1) of the Act. The Minister also notified the Pricing Authority of her intention to issue a direction under the Act.
17. At the 10 August 2012 meeting of the Standing Council on Health, Ministers endorsed the Minister's proposal to alter the Pricing Authority's Work Program.
18. As this Instrument relates solely to the functions and duties of the Pricing Authority, and the activity the Pricing Authority will undertake is not regulatory in nature, this Instrument does not meet the requirements for a Regulation Impact Statement.

Not subject to disallowance

19. Under section 44 of the *Legislative Instruments Act 2003,* this Instrument is not subject to disallowance.

Statement of Compatibility with Human Rights

20. In accordance with section 9 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, a statement of compatibility with human rights has not been completed for this Instrument. This is because that section requires a statement of compatibility to be prepared only for a legislative

instrument to which section 42 of the *Legislative Instruments Act 2003*, and the effect of section 44 of that Act is that section 42 does not apply to this Instrument.