

## **EXPLANATORY STATEMENT**

Issued by the authority of the Minister for Health and Ageing

### ***HEALTH INSURANCE ACT 1973***

## **DECLARATION OF QUALITY ASSURANCE ACTIVITY**

### **UNDER SECTION 124X**

**QAA No. 3/2011**

Part VC of the *Health Insurance Act 1973* (the Act) creates a scheme to encourage efficient quality assurance activities. Those activities help to ensure the quality of health services that are funded by the Government, through Medicare benefits, the Pharmaceutical Benefits Scheme, Public Hospitals and/or Health Program Grants. The scheme encourages participation in such activities by protecting certain information from disclosure, and also by providing some protection from civil liability to certain persons engaged in those activities in good faith, in respect of those activities.

In order for Part VC to apply to an activity, the Minister must make a Declaration pursuant to Section 124X of the Act, that the activity described in the Declaration is a quality assurance activity to which Part VC applies. Regulations 23C to 23G of the *Health Insurance Regulations 1975* (the Regulations) set out the public interest criteria that must be met by quality assurance activities in order to be declared under the section 124X.

This Declaration has effect from the day after registration on the Federal Register of Legislative Instruments. Section 124X(4) of the Act prescribes that, unless sooner revoked, this determination ceases to be in force at the end of 5 years after the instrument of declaration was signed.

The purpose of the Declaration is to declare nine quality assurance activities qualified privilege activities under section 124X of the Health Insurance Act 1973.

An overview of the activities for which the Declaration is made is contained in the [Attachment](#).

Before the Minister can make a declaration, certain requirements must be met.

Firstly, the Minister must be satisfied that the persons engaged in the activity are authorised to do so as described in paragraph 124X(3)(a) of the Act.

The activities described in the Attachment meets the requirement as the persons engaged in them are authorised either by associations of health professionals or research institutions.

Secondly, paragraph 124X(3)(b) of the Act provides that the Minister must be satisfied that it is in the public interest to have Part VC of the Act apply to the activity. In doing so, the Minister must have regard to criteria prescribed by the Regulations. The criteria relevant

to the activities are in regulations 23C, 23D and 23E or 23F and 23G. The activity meets the relevant criteria prescribed by the Regulations.

### CONSULTATION

Consultations regarding the application for declaration were undertaken in May 2011. This included obtaining advice on the potential value of declaring the activity as a quality assurance activity for the purposes of the Act, the methodology used to conduct the activity, and whether the application met the criteria required for declaration, in particular those criteria relating to whether it is in the public interest to declare the activity.

Those consulted included members of the Qualified Privilege Advisory Group, which includes an external clinician; a legal expert; a quality manager working in the field of health care quality assurance; and a consumer representative.

The declaration of the activity will not result in any direct or substantial indirect effect on business.

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

**ATTACHMENT****OVERVIEW OF THE *DECLARATION OF QUALITY ASSURANCE ACTIVITY*  
*UNDER SECTION 124X OF THE HEALTH INSURANCE ACT 1973 – QAA 3/2011*****Breast Implant Registry**

Breast Implant Registry (BIR) is a database of implant prostheses. It contains patient, surgeon and prosthesis details as well as revision information (if appropriate). It is managed by the Australian Society of Plastic Surgeons. Its main objectives are: providing a device register; document performance of breast implants and adverse outcomes; and report outcomes and findings.