Health Insurance (Quality Assurance Activity – Australian Breast Device Registry) Declaration 2024

I, PAUL KELLY, delegate for the Minister for Health and Aged Care, make the following declaration under section 124X of the *Health Insurance Act 1973*.

Dated 2nd April 2024

Professor Paul Kelly
Chief Medical Officer
Department of Health and Aged Care

Contents

Part 1—Preliminary

1 Name

This instrument is the *Health Insurance (Quality Assurance Activity – Australian Breast Device Registry) Declaration 2024*

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 124X(1) of the *Health Insurance Act 1973.*

4 Repeal

This instrument is repealed when it ceases to be in force in accordance with subsection 124X(4) of the *Health Insurance Act 1973*.

5 Schedule

The quality assurance activity described in the Schedule to this declaration is, to the extent that the quality assurance activity relates to health services provided in Australia, declared to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* applies.

Schedule 1—Description of quality assurance activity

1 Name of activity

The name of the quality assurance activity is the Australian Breast Device Registry.

2 Description of activity

This quality assurance activity is operated by the Monash University School of Public Health and Preventive Medicine which tracks the performance of high-risk implantable breast devices and identifies long-term device safety issues for breast implants, tissue expanders and matrices used in reconstructive and cosmetic breast surgery.

Data relating to implantation, revision or explantation of breast devices is collected from participating hospitals and surgeons.

The overall aim is to improve the safety of breast devices for patients in the following ways:

- Collection of population-level data regarding breast devices implanted, revised and explanted, to assist patients, surgeons and hospitals, should a device warning or recall by made by the Therapeutic Goods Administration (TGA).
- Monitoring and reporting the long-term performance of breast devices to identify potential device safety issues, and providing performance information to the TGA, to assist it in its regulatory capacity.
- Monitoring and reporting on potential trends and complications associated with breast device surgery.

De-identified results are reported back to participating clinicians, health service providers and other key stakeholders on the long-term performance of breast implant devices to enhance long-term monitoring and improve patient safety.

De-identified aggregated data is also published in:

- Annual reports produced by the Australian Breast Device Registry
- Academic publications in surgical journals
- Quality and safety reports provided to device companies.