EXPLANATORY STATEMENT

Health Insurance Act 1973

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

Purpose and operation

Part VC of the *Health Insurance Act 1973* (the Act) creates a scheme to encourage efficient quality assurance activities in connection with the provision of health services. Those activities help to ensure the quality of health services that are funded by the Government, including through Medicare benefits and public hospital services. The scheme encourages participation in such activities by protecting certain information from disclosure, and by providing some protection from civil liability to certain persons engaged in those activities in good faith.

The purpose of the *Health Insurance (Quality Assurance Activity – Australian Breast Device Registry) Declaration 2024* (the Declaration) is to declare the Australian Breast Device Registry (the Activity) to be a quality assurance activity to which Part VC of the Act applies.

The Activity is undertaken by Monash University School of Public Health and Preventive Medicine (Monash University). The Activity records and tracks the performance of high-risk implantable breast devices to detect any defects and long-term device safety issues to improve clinical outcomes for procedures that use breast implants, tissue expanders and matrices in reconstructive and cosmetic breast surgeries.

The Activity is primarily designed as a safety activity to protect patients. Data relating to implantation, revision or explantation of breast devices is collected from participating hospitals and surgeons via a data collection form. Once the data collection form is received by the Australian Breast Device Registry, patients are sent a Patient Explanatory Statement. Patients are provided two weeks to opt out after the date the statement is sent. They may also withdraw at any time following this.

The data is analysed to monitor breast device safety, and the performance of surgical procedures. This is used to advise the Therapeutic Goods Administration of any defects and to inform them of the long-term performance of breast devices. The Activity also provides data on the incidence or cause of conditions or circumstances affecting the quality of health care, including feedback to participating sites and clinicians, and to industry in relation to underperforming breast devices. A new dataset will be included to provide outcome-based reports to individual surgeons comparing their complication and revision rates against their peers, with the aim of reducing variation and improving overall outcomes.

Patient data collected is identified and stored in a high security system. Copies of the paper data collection form are kept in secure storage accessible only by the authorised Australian Breast Device Registry staff. Monash Registry Database security is maintained using data encryption, a managed and audited protocol for access, training and accreditation of personnel, role-based access and authentication of data. Data is extracted in de-identified format for analysis, reporting and data sharing purposes. No personal data is released into the public domain.

Authority

Subsection 124X(1) of the Act provides that the Minister may, by legislative instrument, declare a quality assurance activity described in a declaration to be a quality assurance activity to which Part VC of the Act applies. The Declaration declares the Activity, to be a quality assurance activity to which Part VC of the Act applies.

Commencement

The Declaration commences on the day after registration of the instrument on the Federal Register of Legislation.

Consultation

Monash University, as the applicant for declaring the Activity, was consulted in relation to the content of the Declaration. No concerns were raised with the proposed content. Wider consultation was not considered necessary as the quality assurance activity only relates to the gathering of information for the Activity, as conducted by Monash University. The declaration of the Activity will not result in any direct or substantial indirect effect on business.

General

The Declaration is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Declaration are set out in **Attachment A**.

The Declaration is compatible with the rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility with human rights is set out in **Attachment B**.

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

Part 1—Preliminary

Section 1 – Name

This section provides that the name of the Declaration is the *Health Insurance (Quality Assurance Activity – Australian Breast Device Registry) Declaration 2024*.

Section 2 – Commencement

This section provides that the Declaration commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the Declaration is made under subsection 124X(1) of the *Health Insurance Act 1973*.

Section 4 – Repeal

This section provides that the Declaration will be repealed when it ceases to be in force in accordance with subsection 124X(4) of the *Health Insurance Act 1973*.

Subsection 124X(4) of the *Health Insurance Act 1973* provides that a declaration of a quality assurance activity ceases to be in force at the end of 5 years after it is signed, unless sooner revoked.

Section 5 – Schedule

This section provides that the quality assurance activity described in the Schedule is 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

Item 1 – Name of activity

Item 1 provides that the name of the activity is the ‘Australian Breast Device Registry’.

Item 2 – Description of activity

Item 2 of Schedule 1 describes the quality assurance activity as a registry to record and track the performance of high-risk implantable breast devices to detect any defects and long-term device safety issues to improve clinical outcomes for procedures that use breast implants, tissue expanders and matrices in reconstructive and cosmetic breast surgeries.

Data relating to implantation, revision or explantation of breast devices is collected from participating hospitals and surgeons and is analysed to monitor breast device safety, and the performance of surgical procedures. This data provides valuable safety and performance information in a shorter timeframe than is possible through regular population-level and administrative data collection, analysis and reporting of breast device outcome information.

This information is evaluated using long-term follow up data on breast device performance including complication and revision rates. Results are reported back to participating clinicians, health service providers and other key stakeholders, such as the Therapeutic Goods Administration, on the performance of breast implant devices to enhance long-term monitoring and improve patient safety.

De-identified results are reported 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.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

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

This Declaration 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 legislative instrument

The *Health Insurance (Quality Assurance Activity – The Australian Breast Device Registry) Declaration 2024* (the Declaration) declares the Australian Breast Device Registry, conducted by the Monash University School of Public Health and Preventive Medicine, to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* (the Act) applies. Information known solely as the result of the Activity, or documents created solely for the purposes of the Activity, will be covered by Quality Assurance Confidentiality.

Human rights implications

The Declaration engages with the right to health as set out in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Quality Assurance Confidentiality established by Part VC of the Act is aimed at encouraging participation in quality assurance activities that help to ensure that the highest possible health care standards are maintained. The quality assurance activity described in the Declaration will provide participants with a greater degree of confidence and security that their participation is solely for the benefit of improving the safety of breast devices and breast device surgery for patients.

Conclusion

The Declaration is compatible with human rights as it promotes the right to health.

Professor Paul Kelly

Chief Medical Officer

Department of Health and Aged Care