

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Quality Assurance Activity – Australian and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023

Purpose and operation

The *Health Insurance (Quality Assurance Activity – Australian and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023* (the Declaration) declares the Australian and New Zealand Temporomandibular Joint Replacement Registry (ANZTMJRR) to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* (the Act) applies.

Part VC of 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 activity is undertaken by the Australian and New Zealand Association of Oral and Maxillofacial Surgeons (ANZAOMS). ANZAOMS is the peak professional organisation for oral and maxillofacial surgery in Australia and New Zealand and is responsible for the oversight of the Activity. ANZAOMS has an agreement in place with the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) to collect and report on the activity data on behalf of ANZAOMS, with data management contracted to the South Australian Health and Medical Research Institute (SAHMRI).

The ANZTMJRR involves the collection of prospective and retrospective data from Oral and Maxillofacial surgeons for temporomandibular joint replacement (TMJR) procedures undertaken since 2000. The ANZTMJRR is a quality improvement program that will audit clinical outcomes of TMJR procedures in Australia and New Zealand. While the ANZTMJRR is undertaken in Australia and New Zealand, the Declaration applies only to health services provided in Australia. The Activity will identify factors affecting the outcome of TMJR surgery, and educate surgeons, patients, healthcare providers, hospitals, government and industry on the comparative performance of different approaches to TMJR procedures. Data for the Activity will be collected in hospitals and by surgeons undertaking these types of surgery.

Surgical procedure data is collected using a form which is completed either by the surgeon, surgeon administrators or appointed staff within public and private hospitals around Australia. The data will be matched with Patient Reported Outcome Measures (PROMs) using patient responses to survey questions completed pre- and post-surgery about the extent of pain and disability prior to surgery, as well as the extent and timing of recovery and any complications.

The data will be collated and analysed to identify the factors that result in improved outcomes for prostheses, surgical technique and patient selection and will show the cost effectiveness of these procedures.

In phase one of the ANZTMJRR, PROMs data will be collected directly from patients prior to and following surgery. In phase two of the ANZTMJRR, this data will be collected via a secure electronic data capture platform.

Surgeons have the option of including their identifiable code on the proforma for the PROMS data collection if they wish to access data on their own joint replacements. Individual surgeons are not identified, and it is not possible to identify surgeons in the ANZTMJRR reports produced by ANZAOMS or AOANJRR.

ANZTMJRR patients will not be contacted directly by ANZAOMS, SAHMRI or AOANJRR. No individual patient will be identified during analysis or in the report or publications produced by the ANZTMJRR. Patient operative and prostheses data is managed in accordance with the Guidelines for the Protection of Privacy in the Conduct of Medical Research (Australian Government). Personal data collected is for use by the ANZTMJRR only.

Patient consent is approved by the South Australian Human Research Ethics Committee (HREC) in accordance with the National Health Medical Research Council *Guidelines approved under Section 95A of the Privacy Act 1988*.

The SAHMRI will manage data collection, entry, validation and analysis as well as provide secure data storage for the ANZTMJRR. The SAHMRI has security systems in place that limit access to the ANZTMJRR data to SAHMRI and AOANJRR staff only. In addition, there are policies and procedures as well as software barriers to protect personal information. These include the use of codes, passwords and encryption.

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 ANZTMJRR to be a quality assurance activity to which Part VC of the Act applies.

Commencement

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

Consultation

The ANZAOMS, 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 ANZTMJRR.

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

General

This 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 and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023

Part 1—Preliminary

Section 1 – Name

This section provides that the name of the Declaration is the *Health Insurance (Quality Assurance Activity – Australian and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023*.

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 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 and New Zealand Temporomandibular Joint Replacement Registry’.

Item 2 – Description of activity

Item 2 of Schedule 1 describes the quality assurance activity as a program that collects,

analyses and disseminates de-identified prospective and retrospective data from oral and maxillofacial surgeons for temporomandibular joint replacement (TMJR) procedures undertaken since 2000.

The data will be analysed to identify and evaluate the factors that improve standards in prostheses, surgical technique and patient selection for TMJR procedures and educate surgeons, patients, healthcare providers, hospitals, government and industry on the comparative performance of different approaches to TMJR procedures. This will improve the benefit and cost effectiveness of these procedures.

The ANZAOMS will publish de-identified TMJR information to show the use of prostheses and surgical techniques associated with lower revision rates and which contribute to significant improvements in the quality of life of patients. In collaboration with the AOANJRR, ANZAOMS will publish findings in annual reports with information on patient demographics, trends for different types of surgeries undertaken, prosthesis usage and fixation, outcomes including morbidity and mortality as well as prostheses effectiveness and survival rates.

Outcomes will also be published as research papers and presentations of aggregated non-identifiable findings by the ANZTMJRR Clinical Advisor, ANZAOMS members, AOANJRR directors and staff. Extensive reporting will enable stakeholders to evaluate their practice and implement continuous improvement in TMJR outcomes.

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 – Australian and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023

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 – Australian and New Zealand Temporomandibular Joint Replacement Registry) Declaration 2023* (the Declaration) declares the Australian and New Zealand Temporomandibular Joint Replacement Registry (ANZTMJRR), conducted by the Australian and New Zealand Association of Oral and Maxillofacial Surgeons (ANZAOMS), 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 qualified privilege.

The purpose of the activity is to capture, analyse and disseminate de-identified prospective and retrospective data from oral and maxillofacial surgeons for temporomandibular joint replacement procedures undertaken since 2000.

Human rights implications

This 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 Qualified Privilege Scheme 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 this Declaration will provide participants with a greater degree of confidence and security that their participation is solely for the benefit of improving community health care.

This Declaration also engages, but does not limit, the right to privacy as contained in Article 17 of the *International Covenant on Civil and Political Rights*. The Activity involves the collection, storage, security, use, disclosure or publication of de-identified personal information. Aggregated non-identifiable data and findings will be disclosed in the annual report once enough data has been collected for an accurate analysis. Patients, surgeons, hospitals and other stakeholders have access to real-time data specific to them via secure online portals.

Conclusion

This Declaration is compatible with human rights as it promotes the right to health and does not limit the right to privacy.

Professor Paul Kelly

Chief Medical Officer
Department of Health and Aged Care