

## EXPLANATORY STATEMENT

### ISSUED BY THE AUTHORITY OF THE MINISTER FOR HEALTH

#### *HEALTH INSURANCE ACT 1973*

##### *Health Insurance (Quality Assurance Activity) Declaration 2020 (No. 1)*

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 ensure the quality of health services that are funded by the Government, including through Medicare benefits, the Pharmaceutical Benefits Scheme, and 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.

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

The purpose of the *Health Insurance (Quality Assurance Activity) Declaration 2020 (No. 1)* (the Declaration) is to declare the Australian and New Zealand Society of Cardiac and Thoracic Surgeons' (ANZSCTS) Cardiac Surgery Monitoring Program (the Program) to be a quality assurance activity to which Part VC of the Act applies.

The body authorising this activity is the Australasian Cardiac Surgery Research Institution (ACSRI), which is a not-for-profit organisation established by the ANZSCTS for the purpose of undertaking research. The activity will be undertaken by ACSRI who contracts the Department of Epidemiology, Monash University to perform data acquisition and quality assurance functions for cardiac surgery performed in public hospitals in Victoria, New South Wales, South Australia, Western Australia, the ACT and Queensland.

The Program collates cardiac surgery data in an established database and compares the results of adult cardiac surgical procedures and outcomes against an agreed set of Key Performance Indicators (KPIs). The analysis of these results takes into account a patient's risk of complication and highlights surgical procedures and methods used to achieve the most successful patient outcomes.

The declaration applies to the quality assurance analysis process, outcomes of specific quality assurance investigations, any identifying data received and follow up actions with individual surgeons undertaken as part of the Cardiac Surgery Monitoring Program including:

- The general peer review and quality assurance processes of the Program, being the data used in the functionality of the process, the procedures involved in the data collection process and the conclusions of that process; and
- The specific peer review and quality assurance process as applied to individual instances.

The main objective of the Program is to maintain and enhance the quality of adult cardiac surgical care in Australia. Other objectives include to:

- analyse and monitor aggregated information to discover relative underperformance and excellence;
- enact and maintain an effective peer review process, including defined escalation protocols;
- provide comparative information on the standard of cardiac surgery on an individual, unit, state and national level;
- establish Australian-specific risk adjustment algorithms to enable those comparisons of surgical performance;
- conduct and facilitate research on the outcomes of cardiac surgery based on the aggregated information; and

- record details and ultimately track the durability of valve prostheses used in cardiac surgery.

ACSRI will provide regular disclosures of de-identified information about the activity in Annual Reports showing detailed comparisons for cardiac procedures performed each calendar year against the KPIs. Extracts of reports are provided to the Departments of Health and hospitals in participating jurisdictions. Comparative performance data is evaluated quarterly by the quality assurance sub-committee of the Program Steering Committee and ongoing quarterly reports are provided to the Program Steering Committee. ACSRI has agreed to provide copies of de-identified publicly available information to the Minister.

The Program uses electronic methods to collect consistent data from participating surgeons and units and continues to expand with 25 public and 16 private hospital units who are currently contributing information relating to cardiac services identified as eligible under Part VC of the *Health Insurance Act 1973*.

The Program uses electronic methods to collect a consistent set of data from participating surgeons and hospital units, including for cardiac and thoracic surgical procedure items. In particular, data is collected on items 38470 to 38766 on the Medicare Benefits Schedule which attract eligibility for Medicare Benefits payments.

The program has standardised, transparent processes to evaluate the information. All patients are provided with an information sheet on admission for surgery. The program operates on an 'opt out' basis which helps ensure data is collected on as many patients as possible. Patients are fully informed on how to opt-out and who to contact. Where a patient chooses to opt out, this has the effect of removing 'personal identifiers' from the information collected, with patient cardiac surgery procedure information remaining in the Program database.

Case Report Forms are provided to each site for data collection or data can be entered directly into the ANZSCTS Database web system, which is a secure password protected site. Data is entered directly into an online system by Data Managers at most participating sites.

Information held in the database is governed by privacy legislation to protect patient details and keep the information confidential. The data is accessible only to authorised staff of the Program.

Collective data analysis occurs through the reporting system of ANZSCTS for publications in medical journals. Patients are not identified in any reports or publications produced by the Program and the Program is conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007).

Data is retained for at least 15 years to ensure the long-term effectiveness of the Program and to ensure that various heart surgery procedures can be evaluated.

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

## CONSULTATION

ACSRI, as the applicant for declaration of the activity, was consulted in relation to the content of the Declaration. The Commonwealth Department of Health Medicare Reviews Unit was consulted in relation to accreditation requirements for access to Medicare Benefits Schedule items. Wider consultation was not considered necessary as the quality assurance activity relates only to the gathering of information for the ANZSCTS Cardiac Surgery Monitoring Program, as conducted by ACSRI.

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

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

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

Authority: Subsection 124X(1) of the  
*Health Insurance Act 1973*

**Details of the *Health Insurance (Quality Assurance Activity) Declaration 2020 (No. 1)***

Section 1 – Name

This section provides for the Declaration to be referred to as the *Health Insurance (Quality Assurance Activity) Declaration 2020 (No. 1)* (the Declaration).

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 – Cessation

This section provides that the Declaration will cease to be in force at the end of 5 years after it is signed. This is consistent with subsection 124(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 revoked sooner.

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 – Declaration of quality assurance activity

The Schedule provides that the name of the activity is the ‘Australian and New Zealand Society of Cardiac and Thoracic Surgeons’ Cardiac Surgery Monitoring Program’. It describes the quality assurance activity as the peer review and quality assurance analysis process, the outcomes of specific quality assurance investigations, any identifying data received and follow up actions with individual surgeons undertaken as part of the Cardiac Surgery Monitoring Program.

# 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) Declaration 2020 (No. 1)***

This Legislative Instrument 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) Declaration 2020 (No. 1)* (the Declaration) declares the Australian and New Zealand Society of Cardiac and Thoracic Surgeons' Cardiac Surgery Monitoring Program, conducted by the Australasian Cardiac Surgery Research Institution (ACSRI), which is a not-for-profit organisation established by the Australian and New Zealand Society of Cardiac and Thoracic Surgeons for the purpose of undertaking research, to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* (the Act) applies. The activity will be undertaken by ACSRI who contracts the Department of Epidemiology, Monash University to perform data acquisition and quality assurance functions for cardiac surgery performed in public hospitals in Victoria, New South Wales, South Australia, Western Australia, the ACT and Queensland. 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.

### **Human rights implications**

This Declaration engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Right 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 ensure 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 establishing and improving health care outcomes for the community.

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 by involving the collection, storage, security, use and disclosure of personal information. Data is not collected by ACSRI without patient consent, and all information published as a result of this activity is de-identified prior to disclosure.

### **Conclusion**

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

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