

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022*

#### **Authority**

The *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022* (amending instrument) is a declaration made under subsection 124X(1) of the *Health Insurance Act 1973* (Act).

Subsection 124X(1) of the Act provides that the Minister for Health may, by legislative instrument, declare a quality assurance activity to be a quality assurance activity to which Part VC applies. The *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021* (principal instrument) declares the Australian Vigilance and Surveillance System for Organ Donation for Transplantation (Activity) to be a quality assurance activity to which Part VC of the Act applies.

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

#### **Purpose**

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 public hospital services and Health Program Grants as they relate to organ donation and transplantation. The scheme encourages participation in such activities by protecting certain information from disclosure and by providing some protection from civil liability to certain persons in respect of their engagement in those activities in good faith.

The purpose of the amending instrument is to amend the principal instrument to insert a definition of serious adverse event or reaction (SAER). The insertion of a definition of SAER provides certainty as to what the Activity involves.

#### **Consultation**

The Organ and Tissue Authority, as the applicant for declaring the Activity, was consulted in relation to the content of the amending instrument. The amending instrument will not result in any direct or substantial indirect effect on business.

#### **Commencement**

The amending instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

Details of the amending instrument are set out in **Attachment A**.

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

### Section 1 – Name

This section provides that the name of the instrument is the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022* (amending instrument).

### Section 2 – Commencement

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

### Section 3 – Authority

This section provides that the legislative authority for making the amending instrument is subsection 124X(1) of the *Health Insurance Act 1973*.

### Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the amending instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

### Schedule 1 – Amendments

Schedule 1 to the amending instrument amends the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Declaration 2021*.

### Item 1

Item 1 of Schedule 1 inserts a definition of **SAER**. SAER (short for serious adverse event or reaction) means:

- (a) a serious adverse event; or
- (b) a serious adverse reaction.

A serious adverse event means any undesired or unexpected occurrence associated with any stage of an organ donation and transplantation process (from the donation of the organ to the transplantation of the organ) that might:

- (a) lead to:
  - (i) the transmission of a communicable disease to the transplantation recipient; or
  - (ii) the death of, or a life-threatening, disabling or incapacitating condition for, the

transplantation recipient; or

(b) result in, or prolong, hospitalisation or morbidity for the transplantation recipient.

A serious adverse reaction means any unintended response of an organ transplantation recipient, including a communicable disease in the transplantation recipient, that:

(a) might be associated with any stage of the organ donation and transplantation process (from the donation of the organ to the transplantation of the organ); and

(b) either:

(i) is fatal, life-threatening, disabling or incapacitating for the transplantation recipient; or

(ii) results in, or prolongs, hospitalisation or morbidity for the transplantation recipient.

## **Item 2**

Item 2 of Schedule 1 amends clause 2 of Schedule 1 in the principal instrument by omitting the words “Serious Adverse Events and Reactions (SAER)”, substituting them with the acronym “SAERs”. This is a consequential amendment, resulting from the insertion of the definition of SAER in item 1.

## 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 Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022*

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 – Australian Vigilance and Surveillance System for Organ Donation and Transplantation) Declaration 2021* (principal instrument) declares the Australian Vigilance and Surveillance System for Organ Donation for Transplantation (Activity) to be a quality assurance activity to which Part VC of the *Health Insurance Act 1973* (Act) applies. The Activity will be conducted by the Australian Organ and Tissue Donation and Transplantation Authority, also known as Australian Organ and Tissue Authority (OTA). The OTA is a non-corporate Commonwealth entity established by s 8(1) of the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* for the purpose of working with states and territories, clinicians and the community sector to deliver the Australian Government's national program to improve organ and tissue donation and transplantation outcomes in Australia. Information obtained solely as the result of conducting the Activity, or documents created solely for the purposes of the Activity, will be covered by qualified privilege.

The purpose of the *Health Insurance (Quality Assurance Activity – Australian Vigilance and Surveillance System for Organ Donation for Transplantation) Amendment (Serious Adverse Event or Reaction) Declaration 2022* (amending instrument) is to amend the principal instrument to insert a definition of serious adverse event or reaction (SAER).

### Human rights implications

This amending instrument engages 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 standards 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 Activity will provide participants with a greater degree of confidence and security that their participation is for the benefit of improving healthcare outcomes for patients involved in deceased donor organ donation and transplantation. The insertion of a definition of SAER provides certainty as to what the Activity involves.

This amending instrument 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, disclosure or publication of personal information. Data collected as part of the Activity will be de-identified to ensure that no individuals are identified prior to analysis or disclosure of the information. The OTA will publish a range of information relating to the Activity, including annual reports on the Activity, Vigilance and Surveillance

Expert Advisory Committee quarterly communiques, recommendations for clinical practice improvements and contributions to the NOTIFY Library database.

### **Conclusion**

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

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